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April 3, 2023

VIA ECF

Hon. Julien Xavier Neals, U.S.D.J.
United States District Court for the District of New Jersey
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Mylan Pharm. Inc. v. Teva Pharm. Indus. Ltd., et al.*, Civil Action No. 2:21-cv-13087 (JXN-JSA)

Dear Judge Neals:

This firm, along with Goodwin Procter LLP, represents Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva") in the above-referenced matters. We are writing to respond to the letter submitted by Mylan Pharmaceuticals Inc. ("Mylan"), dated March 24, 2023 (ECF No. 111) ("Mylan Letter"), regarding the decision in *Regeneron Pharmaceuticals, Inc v. Amgen Inc.*, No. 1:22-cv-697 (D. Del.).¹ In addition, Teva writes to bring to the Court's attention the recent decision in *In re HIV Antitrust Litig.*, No. 3:19-cv-02573 (N.D. Cal.), which supports Teva's arguments in its motion to dismiss.²

I. Regeneron v. Amgen

In this case, Regeneron alleged that Amgen entered into exclusive contracts with specific Pharmacy Benefit Managers ("PBMs"), which conditioned Amgen's payment of rebates for separate classes of drug products on PBMs giving Amgen's cholesterol drug (Repatha) exclusive formulary position over Regeneron's competing cholesterol drug (Praluent). See Complaint ¶¶ 14-17, No. 1:22-cv-697 (D. Del.), ECF No. 1 ("Regeneron Compl."); see also Exhibit A, at 1-5. Regeneron alleged that these cross-product exclusive rebate agreements constituted unlawful bundling and below-cost pricing in violation of the Sherman Act, see Regeneron Compl. at 68-83, and the magistrate judge and district court denied Amgen's motion to dismiss.

The allegations in *Regeneron* are markedly different than those Mylan has presented, and the court's reasoning for denying the motion to dismiss does not apply here. In particular, Mylan does not plausibly allege that Teva engaged in a "multiproduct rebating scheme" to exclude Mylan. Mylan Letter at 1. Unlike Amgen's alleged efforts to leverage rebates for products where

¹ The magistrate judge's report and recommendation is attached as **Exhibit A** to Mylan's letter, and the district court's order adopting the report and recommendation is attached as **Exhibit B**.

² The *HIV Antitrust Litigation* decision is attached as **Exhibit 1** to this letter.

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it faced no competition from the plaintiff (Regeneron), the alleged post-generic entry rebates for favorable formulary placement that Mylan challenges imposed no such disadvantage for Mylan. The FDA granted approval for Mylan to market 20 mg and 40 mg generic Copaxone products **on the same day**, Mylan Compl. ¶¶ 79-80 (ECF No. 1), meaning that at all times for this theory, Mylan could compete with Teva across **both** dosages. As Teva explained in its motion to dismiss, bundling is not a mode of exclusion when rivals can compete with offerings across the product line. See Teva Br. 46 (ECF No. 55-1) (citing, e.g., *Shire US, Inc. v. Allergan Inc.*, 375 F. Supp. 3d 538, 557 (D.N.J. 2019)). As a result, *Regeneron*'s observation that even above-cost "bundled discounts" may be anticompetitive does Mylan no good. See Exhibit A at 14 (citing *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003)). *LePage's* has been limited to "cases in which a single-product producer is excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across multiple different product lines." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 274 n.11 (3d Cir. 2012); see *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405 (3d Cir. 2016) (similar). Nothing like that is alleged here, as Mylan was fully capable of competing with Teva for preferential formulary placement across both dosages of Copaxone.

For the same reason, *Regeneron* offers no guidance as to whether the price-cost test or the general rule of reason should apply to Mylan's allegations challenging Teva's alleged rebate agreements. See Teva Br. 43-51. The price-cost test applies only to **above-cost** pricing (Teva Br. 44), but *Regeneron* specifically alleged that Amgen's bundled rebates resulted in **below-cost** pricing for its cholesterol drug. See Exhibit A at 14 (concluding that *Regeneron*'s complaint plausibly alleged that when the bundled rebate is allocated only to the contested product, it resulted in that product "being priced below cost"). Unsurprisingly then, Amgen did not even try to argue that the price-cost test applied to its alleged discounts. By contrast, Mylan's Complaint expressly alleges that Copaxone prices remained **above** cost. See Teva Br. 44 (citing Mylan Compl. ¶ 208). And, as Teva explained in its motion, the price-cost test applies with full force to exclusive dealing arrangements where price is the "clearly predominant mechanism of exclusion," as it was with Teva's alleged rebates. See Teva Br. 44 (quoting *ZF Meritor, LLC*, 696 F.3d at 275).

Finally, even assuming the rule of reason applies here, the *Regeneron* decision does not aid Mylan's efforts to sustain its exclusive dealing allegations under that standard. As Teva has explained (and *Regeneron* recognized), courts assess whether exclusive dealing arrangements are anticompetitive by evaluating, among other things, the duration and terminability of contracts, whether the dominant firm engaged in coercion, and the percentage of the market foreclosed. See Teva Br. 47-48. Although the *Regeneron* court declined to dismiss based on these factors, *Regeneron*'s complaint included key factual assertions that are absent here, including the identity of specific PBMs that allegedly entered exclusive contracts with Amgen and the PBMs' respective market shares. See Exhibit A, at 11; see also Exhibit B at 3 (concluding that *Regeneron* had "pledged its case with specificity"). Here, by contrast, Mylan's complaint refers vaguely to "key PBMs," without alleging which PBMs or their market shares, and also acknowledges that Teva offered PBMs a "range" of contractual terms—including **non-exclusive** positions alongside generic products. See Teva Br. 47-48, 50-51. Moreover, the magistrate judge's conclusion in *Regeneron* that the issue of contract duration should not be considered on a motion to dismiss is contrary to the weight of authority. See, e.g., *Shire*, 375 F. Supp. 3d at 558 (dismissing exclusive dealing claim where the relevant contracts were "for one year and are open to competitive bidding on an annual basis"); *Int'l Constr. Prods. LLC v. Caterpillar Inc.*, 2016 WL 264909, at *5, *6 (D. Del. Jan. 21, 2016) (dismissing exclusive dealing claim in part because of the absence of allegations regarding the contracts' duration or the "existence of coercion"); *Power Analytics Corp.*

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v. *Operation Tech., Inc.*, 2018 WL 10231437, at *22, *24 (C.D. Cal. July 24, 2018) (dismissing Section 2 claim because complaint did “not contain any allegations as to coercion, ease of termination, or duration”), *aff’d*, 820 F. App’x 1005 (Fed. Cir. 2020).

II. In re HIV Antitrust Litigation

In its Motion to Dismiss, Teva has argued that Mylan’s allegations that Teva initially priced its 40 mg Copaxone product below its 20 mg product does not plausibly suggest coercion to support a product-hop theory, *see* Teva Br. 34, and that Mylan cannot state a Sherman Act claim by aggregating perfectly lawful conduct into an overall-scheme theory, Teva Reply Br. 2-6 (ECF No. 57). The recent decision in *In re HIV Antitrust Litigation*, No. 3:19-cv-02573 (N.D. Cal.) (**Exhibit 1**), supports both of these arguments.

The plaintiffs in *HIV Antitrust Litigation* alleged that a drug manufacturer engaged in a product hop “to switch HIV patients” to a different line of products. Exhibit 1, at 2, 5-8. In particular, the plaintiffs asserted that the defendant executed a product hop by “manipulat[ing] the price” of its products, “increas[ing] the price of” the older product “by 4.9% … and then by 6.9%” so the newer product was priced lower. Exhibit 1, at 7. The district court rejected the plaintiffs’ reliance on a theory of “price separation,” concluding that mere price separation did not rise to the level of coercion as a matter of law. *Id.* at 14-15. That same reasoning dooms Mylan’s effort to base its product-hop claim on an alleged “9.8%” price increase of Copaxone 20 mg, *see* Mylan Compl. ¶ 121—an alleged increase that is less than the increase in *HIV Antitrust Litigation* found not to be coercive, and which was consistent with standard price adjustments for Copaxone products. *See* Teva Br. 34.

The *HIV Antitrust Litigation* decision also supports Teva’s argument that Mylan cannot sweep lawful conduct into an overall scheme theory of liability. Teva Reply Br. 2-6. The product-hop claim in that case was only one of several theories of liability asserted by the plaintiffs. *See* Exhibit 1, at 2-3. But upon finding the product-hop theory non-viable, the district court dismissed that claim from the case, both as a stand-alone claim and as part of an alleged “overall scheme.” *See* Exhibit 1, at 17-18 (declining to allow product-hop theory to move forward, even as part of an “overall … scheme”). That approach is consistent with Teva’s argument that Mylan’s Sherman Act claim cannot proceed based on conduct that is procompetitive, such as alleged above-cost rebating and price incentives, notwithstanding the “overall scheme” allegation.

* * * * *

We thank the Court for its ongoing attention to this matter and are available should Your Honor or Your Honor’s staff have any questions or need anything further.

Respectfully submitted,

s/Liza M. Walsh

Liza M. Walsh

cc: Counsel of Record (via ECF and Email)

EXHIBIT 1

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7 IN RE HIV ANTITRUST LITIGATIONCase No. [19-cv-02573-EMC](#)8
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**ORDER GRANTING IN PART AND
DENYING IN PART DEFENDANTS'
MOTIONS FOR SUMMARY
JUDGMENT**

Docket Nos. 1491-1494, 1501

In this antitrust action, Plaintiffs have sued pharmaceutical companies that manufacture and sell drugs used to treat HIV. Defendants are brand manufacturers Gilead and Janssen as well as generic manufacturer Teva. Plaintiffs allege that the brand companies engaged in anticompetitive conduct designed to stave off generic competition and/or that Teva conspired in that endeavor to its benefit.¹

Currently pending before the Court are multiple summary judgment motions. Having considered the parties' briefs and accompanying submissions, as well as the oral argument of counsel, the Court hereby **GRANTS** Defendants' motion on the TAF claims, **DENIES** Plaintiffs' motion on market power, **DENIES** Plaintiffs' motion on the NGR claims, **GRANTS** in part and

¹ Some Plaintiffs have filed class actions; others have filed individual actions. The class actions are brought by the End-Purchaser Plaintiffs ("EPPs") and the Direct-Purchaser Plaintiffs ("DPPs"). Individual actions have been brought by the Retailer Plaintiffs, United HealthCare, and the Individual Health Plan Plaintiffs.

As for Defendants, several Gilead entities and several Janssen entities have technically been sued (as well as Teva). For convenience, the Court refers to the Gilead entities collectively as "Gilead" and the Janssen entities collectively as "Janssen." Although Gilead, Janssen, and Teva are all Defendants in this action, not all Plaintiffs have sued all Defendants. BMS was previously a defendant in the suit but all claims against it appear to have been settled.

1 **DENIES** in part Defendants' motion on the NGR claims, and **DENIES** Defendants' motion on the
2 MFE/MFEP claims.

3 Also pending before the Court are *Daubert* motions that were filed in conjunction with the
4 summary judgment motions. After briefing on the motions was completed, the parties agreed that
5 most, if not all, did not need to be decided in order for the Court to adjudicate the summary
6 judgment motions. The Court agrees and therefore defers ruling on the bulk of the motions. The
7 Court addresses only a subset of Defendants' *Daubert* motions. That specific portion of
8 Defendants' *Daubert* motions is **DENIED**.

9 **I. GENERAL BACKGROUND**

10 The Court's prior orders have outlined the antitrust claims brought by Plaintiffs. *See, e.g.*,
11 *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 573 (N.D. Cal. 2020) (order on motion to dismiss);
12 Docket No. 1388 (class certification order). The Court assumes familiarity with those orders. For
13 purposes of this order, the Court provides a brief overview only.

14 Plaintiffs' antitrust claims, in essence, are predicated on three categories of alleged
15 anticompetitive conduct.

- 16 • **TAF claims.** One of the primary drugs used to treat HIV is tenofovir, which is
17 manufactured by Gilead. TDF was the first tenofovir drug made by Gilead; TAF
18 was its successor. According to Plaintiffs, in order to extend the life of its tenofovir
19 franchise, Gilead delayed development of TAF until a generic version of TDF was
20 imminent and then used anticompetitive techniques to switch HIV patients over
21 from TDF-based drugs to TAF-based drugs.
- 22 • **NGR claims.** HIV is currently treated through a "cocktail" (*i.e.*, combination) of
23 drugs. Gilead and Janssen, as well as Gilead and BMS, entered into collaboration
24 agreements so that they could combine certain of their drugs together (sometimes
25 making a complete HIV treatment regimen). The combination drugs are known as
26 fixed-dose combination drugs ("FDCs").² The brand manufacturers' collaboration

28 ² When an FDC is a complete HIV treatment regimen, it is known as a single-tablet regimen
("STR").

1 agreements contain what Plaintiffs have called No-Generic Restraints (“NGRs”).³
 2 The NGRs are noncompete provisions – *i.e.*, provisions that prevent a collaborator
 3 from offering an identical or near identical FDC that competes with the joint
 4 venture’s FDC. Essentially, they provide that, even if one collaborator’s
 5 component drug loses its patent protection (*i.e.*, a generic version now becomes
 6 available), the other collaborator is barred from making a FDC comprised of its
 7 own component drug and a generic version of the first collaborator’s component
 8 drug.

9 • **MFE/MFEP claims.** Teva filed what is known as abbreviated new drug
 10 applications (“ANDAs”) so that it could manufacture generic versions of certain
 11 FDCs affiliated with Gilead – namely, Truvada and Complera. Both drugs have
 12 FTC (a Gilead drug) as a component. Gilead sued Teva for infringement of its
 13 FTC patents. After a bench trial, but before closing argument and a final decision,
 14 Gilead and Teva settled their dispute. Under the settlement agreement, Teva agreed
 15 to delay its entry into the market (which was a benefit to Gilead). In exchange,
 16 Gilead agreed to a provision that gave Teva “most favored entry” and/or “most
 17 favored entry plus” (“MFE” and/or “MFEP”).⁴ The MFE/MFEP provision is
 18 essentially an acceleration provision. Most notably, it provided that, if Gilead were
 19 to give another manufacturer a license to enter the market and that manufacturer’s
 20 entry date was earlier than the one that had been given to Teva, then Teva’s entry
 21 date would be accelerated so that it would be 180 days earlier than the one given to
 22 the manufacturer.

23 As indicated above, Gilead is implicated in all three of Plaintiffs’ claims, Janssen is
 24

25 ³ Because the Court has used the term “NGR” in its prior orders, it continues to do so here. The
 26 Court recognizes, however, that Defendants disagree with the use of that term, and it makes no
 27 ruling here as to what term should be used before the jury at trial.

28 ⁴ Similar to above, the Court continues to use the terms “MFE” and “MFEP” even though
 Defendants disagree with the use of those terms. The Court makes no ruling as to what terms
 should be used before the jury at trial.

1 implicated in the NGR claims only, and Teva is implicated in the MFE/MFEP claims only.
2 Although the claims are discrete, Plaintiffs maintain that they should be considered collectively as
3 to Gilead. Plaintiffs take the position that Gilead had a scheme to dominate the market in
4 “foundational” HIV drugs, and its conduct in all three categories above was a part of that scheme.
5 *See Opp’n at 48.* Plaintiffs also assert that there is a narrative tie between some of the claims –
6 *e.g.*, Gilead’s collaboration agreements with Janssen and BMS, which contain NGRs, gave
7 extended protection to TDF and thereby gave Gilead more time to move over HIV patients from
8 TDF-based drugs to TAF-based drugs.

9 **II. LEGAL STANDARD**

10 In their pending motions for summary judgment, Defendants have moved for relief on all
11 three claims. If Defendants’ motions are granted, the case would be disposed of in its entirety.
12 Plaintiffs have moved for partial summary judgment only. Specifically, Plaintiffs argue that
13 Defendants undisputedly have market power for certain drugs (implicated in the NGR and
14 MFE/MFEP claims). Plaintiffs also argue that they are entitled to summary judgment on the NGR
15 claims.

16 Federal Rule of Civil Procedure 56 provides that a “court shall grant summary judgment
17 [to a moving party] if the movant shows that there is no genuine dispute as to any material fact and
18 the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). An issue of fact is
19 genuine only if there is sufficient evidence for a reasonable jury to find for the nonmoving party.
20 *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). “The mere existence of a
21 scintilla of evidence . . . will be insufficient; there must be evidence on which the jury could
22 reasonably find for the [nonmoving party].” *Id.* at 252. At the summary judgment stage, evidence
23 must be viewed in the light most favorable to the nonmoving party and all justifiable inferences
24 are to be drawn in the nonmovant’s favor. *See id.* at 255.

25 Where a defendant moves for summary judgment based on a claim for which the plaintiff
26 bears the burden of proof, the defendant need only point to the plaintiff’s failure “to make a
27 showing sufficient to establish the existence of an element essential to [the plaintiff’s] case.”
28 *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

1 Where a plaintiff moves for summary judgment on claims that it has brought (*i.e.*, for
2 which it has the burden of proof), it “must prove each element essential of the claims . . . by
3 undisputed facts.” *Cabo Distrib. Co. v. Brady*, 821 F. Supp. 601, 607 (N.D. Cal. 1992); *see also*
4 *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986) (stating that, “if the movant bears
5 the burden of proof on an issue, either because he is the plaintiff or as a defendant he is asserting
6 an affirmative defense, he must establish beyond peradventure all of the essential elements of the
7 claim or defense to warrant judgment in his favor”) (emphasis omitted).

8 Below the Court addresses Defendants' motion on the TAF claims first. Next, it considers
9 Plaintiffs' motion on market power (since it has bearing on both the NGR claims and the
10 MFE/MFEP claims). A discussion of the cross-motions on the NGR claims follows, and then a
11 discussion of the MFE/MFEP claims.

III. TAF CLAIMS

13 Plaintiffs assert the TAF claims against Gilead only. Gilead has moved for summary
14 judgment on the TAF claims in their entirety.

15 A. Relevant Background

16 Tenofovir is a drug used to treat HIV. It cannot be administered orally by itself. However,
17 Gilead has developed two “prodrugs” of tenofovir that allow it to be swallowed: TDF and TAF.
18 TAF is essentially the successor drug to TDF.

19 In 2001, Viread (TDF) was approved by the FDA. *See* Hardy Rpt. ¶ 85. Shortly after
20 Viread's approval, Gilead began developing TAF. *See* Hardy Rpt. ¶ 95.

In 2003, Gilead completed a phase 1b clinical trial for TAF. *See* Hardy Rpt. ¶ 96. Although the results for TAF looked promising, *see* Hardy Rpt. ¶ 97 (indicating that, based on the results, TAF “could prove to be a safer form of TDF for patients with kidney and bone disease”), Gilead decided not to move forward with phase 2 and 3 studies for TAF. Rather, in October 2004, Gilead announced it was discontinuing TAF’s development. *See* Hardy Rpt. ¶ 100. According to Plaintiffs, although Gilead publicly claimed that TAF was not sufficiently differentiated from TDF to warrant continued development, *see* Hardy Rpt. ¶ 100; Follansbee Rpt. ¶ 179, Gilead had other reasons for discontinuing development. Specifically, Gilead wanted to delay introducing TAF

1 until 2015, which was a few years before the TDF patents would expire in 2017, so that Gilead
2 could use TAF as a means of extending the life of its tenofovir franchise. *See, e.g.*, Huttinger
3 Decl., Ex. 119 (internal Gilead memo, dated 9/18/2003) (doing a financial analysis that “assumes
4 . . . Gilead will develop [TAF] to replace both [TDF] and the TDF/FTC combination product in
5 order to extend the exclusivity of the tenofovir franchise by four years”).

6 Several years later, in or about 2010, Gilead reopened development of TAF. Plaintiffs
7 maintain that Gilead followed the playbook it had set out earlier: Gilead would introduce TAF and
8 move HIV patients over from TDF-based drugs to TAF-based drugs before the TDF patents could
9 expire in 2017 or 2018. *See, e.g.*, Huttinger Decl., Ex. 131 (internal Gilead memo, dated
10 5/12/2010) (stating that TAF “should be considered for development as a stand alone agent and in
11 fixed dose combination with FTC as a replacement for [TDF] based on the following: [*inter alia*]
12 Additional patent life beyond [TDF]”); Huttinger Decl., Ex. 132 (internal Gilead email, dated
13 5/5/2010) (commenting that Gilead should “try to initiate new patients on [TAF] and switch as
14 many TDF patients as possible to [TAF] within the window of launch (2015) and TDF patent
15 expiration (2017/2018)”; Huttinger Decl., Ex. 133 (internal Gilead memo, dated 6/2010) (stating
16 that “[t]he success of [TAF] would stem from convincing HIV prescribers to switch as many
17 patients as possible from a TDF-containing regimen to a [TAF]-containing regimen between 2015
18 and 2018”).

19 Plaintiffs assert that, to channel HIV patients from TDF-based drugs to TAF-based drugs,
20 Gilead engaged in the following conduct:

21 **1. Safety.** Gilead promoted its TAF-based drugs as safer compared to its TDF-based
22 drugs. Gilead promoted the safety of TAF-based drugs in three primary ways.

23 First, Gilead intentionally degraded the safety of Stribild, a TDF-based drug. Stribild is a
24 FDC (comprised of TDF/FTC/EVG/COBI) that includes a booster (COBI). The booster is used so
25 that another component in Stribild (EVG) can be taken once daily instead of twice a day. *See*
26 Gant Decl., Ex. 20 (Bischofberger Depo. at 214). However, coadministration of tenofovir with a
27 booster increases tenofovir exposure and therefore kidney toxicity. *See* Hardy Rpt. ¶ 118. In spite
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1 of this, Gilead kept the dose of TDF in Stribild at a full 300 mg.⁵ *See* Hardy Rpt. ¶ 121 (stating
 2 that 300 mg was a “dosage only demonstrated to be appropriate for achieving efficacy *without* a
 3 booster”) (emphasis in original).

4 In contrast, Gilead took a different approach with Genvoya, the TAF-based drug that was
 5 the successor to Stribild. Genvoya (comprised TAF/FTC/EVG/COBI) has the same components
 6 as Stribild except that it contains TAF instead of TDF. For Genvoya, Gilead did adjust the dosage
 7 of TAF down (from 25 mg to 10 mg) because the booster (COBI) increases tenofovir exposure.
 8 *See* Hardy Rpt. ¶ 119.

9 Second, Gilead designed clinical studies for its TAF-based drugs to make them look
 10 superior to TDF-based drugs. Specifically, Gilead chose to compare Genvoya with Stribild, even
 11 though Stribild had a standard dose of boosted TDF while Genvoya had a reduced dose of boosted
 12 TAF. *See* Hardy Rpt. ¶ 131. Plaintiffs emphasize that Gilead never compared unboosted TAF
 13 regimens and unboosted TDF regimens. *See* Opp’n at 43.

14 Third, Gilead deceptively marketed TAF’s safety to physicians, HIV patients, and payors –
 15 e.g., relying on the flawed Genvoya-Stribild comparison and concealing that TAF was safer for
 16 only a “modest subset of TDF patients – those with acute renal/bone conditions (~17%).” Opp’n
 17 at 44-45.

18 **2. Pricing.** Gilead manipulated the price of TDF-based Stribild. To make TAF-based
 19 Genvoya more attractive over Stribild, Gilead increased the price of Stribild two times in 2016 –
 20 by 4.9% in January 2016 and then by 6.9% in July 2016. *See* Mot. at 10. This put Stribild at a
 21 12% premium over Genvoya, even though Genvoya was the newer drug. And this translated to a
 22 difference of about \$4,000 per year in terms of wholesale acquisition cost. *See* Rubinfeld Reb.
 23 Rpt. ¶ 142 (“[G]iven the annual WAC cost of Stribild and Genvoya was \$37,595 and \$33,525 by
 24 the end of 2017 respectively, Gilead had created a substantial premium of more than \$4,000 per
 25 patient per year.”). The pricing difference affected payors’ formulary coverage decisions.⁶ *See*,

27 ⁵ When Viread (TDF) was approved in 2001, it was at a dosage of 300 mg. *See* Follansee Rpt. ¶
 28 87. In other words, 300 mg is the approved dosage of TDF.

⁶ As explained by Plaintiffs’ expert, Dr. Rubinfeld, health plans have “mechanisms to encourage

1 e.g., Huttinger Decl. Ex. 196 (██████████) (noting that “[a] therapeutic substitution from
 2 Stribild to Genvoya and from Complera to Odefsey has been approved . . . [;] [n]ew contracting
 3 has made Genvoya and Odefsey preferred over Stribild and Complera because they are lower in
 4 cost”).

5 Thus, according to Plaintiffs, through safety manipulation and differential pricing, Gilead
 6 put pressure on doctors, HIV patients, and payors to transition from TDF-based drugs to TAF-
 7 based drugs.

8 Finally, Plaintiffs point out that, when Gilead did make its TAF-based drugs available, it
 9 chose to withhold release of TAF as a standalone drug for HIV treatment. While Gilead did
 10 launch a standalone version of TAF, it did so only for an indication of hepatitis, and not for an
 11 indication of HIV. Gilead did this even though there was demand for standalone TAF for HIV
 12 purposes, *see* Huttinger Decl., Ex. 200 (internal Gilead email, dated 3/1/2016) (noting that
 13 “[d]emand for standalone TAF for HIV remains and community is going to continue to advocate
 14 for it”), and even though Gilead stood to profit from a release of standalone TAF for HIV
 15 purposes. *See, e.g.*, Huttinger Decl., Ex. 199 (internal Gilead document, dated 10/22/2012) (at
 16 Figure 10, forecasting profits for “TAF Single Agent” in the United States – as high as \$62 million
 17 for the year 2018). Gilead’s internal documents reflected that it believed there was “[s]ome
 18 commercial risk . . . associated with having TAF SA [standalone] for HIV available in the US,”
 19 with the “primary risk” being that “it may facilitate the break-up of STRs, an approach that is
 20 inconsistent with the ongoing Gilead STR platform,” and another risk being “the availability of
 21 TAF SA may encourage its use with generics.” Huttinger Decl., Ex. 202 (internal Gilead
 22 document, dated 12/6/2013).

23 B. Scope of TAF Claims

24 As an initial matter, the Court takes note that, at the hearing, Plaintiffs clarified the scope
 25 of their TAF claims. As indicated above, the TAF claims appeared to be based on three different
 26

27 their members to use generic drugs,” including by putting generic drugs into “a preferred tier in
 28 [the] health plans’ formularies.” Rubinfeld Rpt. ¶ 100. “Consumers generally pay lower co-
 payments for drugs that are on the preferred tier” Rubinfeld Rpt. ¶ 101.

1 acts by Gilead: (1) Gilead’s decision to delay development and introduction of TAF into the
 2 market; (2) Gilead’s pressure on HIV patients to move from TDF-based drugs to TAF-based
 3 drugs; and (3) Gilead’s decision to release standalone TAF without an indication for HIV. At the
 4 hearing, Plaintiffs conceded that they are *not* asserting that Gilead engaged in anticompetitive
 5 conduct by (1) deciding to delay development and introduction of TAF into the market and (3)
 6 deciding to release standalone TAF without an HIV indication. Implicitly, Plaintiffs’ concession
 7 was based on authority holding that, “as a general rule, ‘any firm, even a monopolist, may . . .
 8 bring its products to market whenever and however it chooses.’”⁷ *Foremost Pro Color, Inc. v.
 9 Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983).

10 Plaintiffs, however, maintain that Gilead’s conduct in (1) and (3) could still be relevant
 11 *evidence* in their case, including with respect to Gilead’s anticompetitive conduct based on (2).
 12 Plaintiffs also assert that they *do* have a claim for an antitrust violation based on (2) – *i.e.*, Gilead’s
 13 forced “switching” of HIV patients from TDF-based to TAF-based drugs. According to Plaintiffs,
 14 Gilead was motivated to delay on TAF (*i.e.*, (1)) so that it could maximize profits from TDF
 15 without worrying about TAF cannibalizing TDF sales; when Gilead did reopen development of
 16 TAF, it did so in order to transition HIV patients to TAF-based drugs when the TDF patents were
 17 due to expire, and, in the meantime, the NGRs would give additional protection to TDF so that
 18 Gilead had time to move patients over.

19 For purposes of summary judgment, the Court need only address the switching (or
 20 “product hopping”) claim (*i.e.*, (2)). Both parties agreed that the issue of whether (1) and (3)
 21 should be admitted as evidence is one that can be dealt with at a time closer to trial. The Court
 22 notes, however, that Plaintiffs’ evidentiary arguments are not entirely without force, at least with
 23 respect to (1). The Court now turns to the switching/product hopping claim.

24

25 ⁷ At the hearing, Plaintiffs were not able to articulate how either of the decisions above could
 26 have, *e.g.*, facilitated the anticompetitive conduct that Plaintiffs are challenging (such as the forced
 27 transition of HIV patients from TDF-based to TAF-based drugs). *See Staley v. Gilead Scis., Inc.*,
 28 446 F. Supp. 3d 578, 614 (N.D. Cal. 2020) (taking note of a Second Circuit case holding that new
 product introductions are not automatically immune from antitrust scrutiny but that “‘it is not the
 product introduction itself, but some associated conduct, that supplies the [antitrust] violation’”)
 (emphasis omitted).

1 C. Switching/Product Hopping Claim

2 With respect to the switching/product hopping claim, the Court begins with the legal
 3 parameters of the claim. Particularly instructive is the Second Circuit's decision in *New York v.*
 4 *Actavis PLC*, 787 F.3d 638 (2d Cir. 2015) (hereinafter “*Namenda*”).⁸ There, the state of New
 5 York filed an antitrust suit against affiliated pharmaceutical companies based on their conduct
 6 related to Alzheimer’s drugs. The companies had an Alzheimer’s drug known as Namenda IR,
 7 which was nearing the end of its patent exclusivity in 2015. The companies then introduced a new
 8 drug known as Namenda XR which would have patent exclusivity until 2029. *See id.* at 642.
 9 Both Namenda IR and Namenda XR had the same active ingredient and the same therapeutic
 10 effect. The only real medical difference was that Namenda IR had to be taken twice a day, and
 11 Namenda XR only once a day. *See id.* at 647. However, once a generic version of Namenda IR
 12 became available, state drug substitution laws would not allow a pharmacist to dispense generic
 13 Namenda IR if a patient were prescribed Namenda XR because generic Namenda IR was only
 14 AB-rated for Namenda IR, and not Namenda XR. *See id.* at 645 (“To receive an AB-rating, a
 15 generic must not only be bioequivalent but pharmaceutically equivalent to the brand drug,
 16 meaning it has the same active ingredient, dosage form, strength, and route of administration as
 17 the brand drug.”).

18 When the companies introduced Namenda XR to the market, they made an active effort to
 19 convert patients from Namenda IR to Namenda XR, precisely because of the “patent cliff” that IR
 20 was facing. Initially, the companies sold both IR and XR “but stopped actively marketing IR.
 21 During that time, they [also] spent substantial sums of money promoting XR to doctors,
 22 caregivers, patients, and pharmacists”; “sold XR at a discounted rate, making it considerably less
 23 expensive”; and “issued rebates to health plans to ensure that patients did not have to pay higher
 24 co-payments for XR.” *Id.* at 648. The Second Circuit called this effort to convert patients to XR a
 25 “soft switch.”

26 About half a year later, the companies changed tactics and adopted a “more direct

27
 28 ⁸ Because there is a Supreme Court case also commonly referred to as *Actavis*, the Court shall
 refer to this Second Circuit decision as *Namenda*.

1 approach” because their “internal projections estimated that only 30% of Namenda IR users would
 2 voluntarily switch” to XR before the entry of generic IR. *Id.* The companies publicly announced
 3 that they would be discontinuing IR – *i.e.*, withdrawing it from the market. The court called this
 4 effort a “hard switch” or “forced switch.” *See id.*

5 The state of New York filed suit and sought a preliminary injunction to stop the companies
 6 from restricting access to Namenda IR during the course of the litigation. The district court
 7 granted the preliminary injunction, and, on appeal, the Second Circuit affirmed.

8 In so ruling, the Second Circuit first took note of “[w]ell-established case law mak[ing]
 9 clear that product redesign is anticompetitive when it coerces consumers and impedes
 10 competition.” *Id.* at 652. Although “neither product withdrawal nor product improvement alone
 11 is anticompetitive[,] . . . when a monopolist *combines* product withdrawal with some other
 12 conduct, the overall effect of which is [1] to coerce consumers rather than persuade them on the
 13 merits and [2] to impede competition, its actions are anticompetitive under the Sherman Act.” *Id.*
 14 at 653-54; *see also Allied Ortho. Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 994,
 15 1002 (9th Cir. 2010) (finding no antitrust violation because the undisputed evidence showed that
 16 the new design was “an improvement over the previous design” and there was “no evidence that
 17 Tyco used its monopoly power to force customers to adopt its new product”; acknowledging that
 18 “[a] monopolist’s discontinuation of its old technology may violate Section 2 if it effectively
 19 forces consumers to adopt its new technology”).

20 Regarding the element of consumer coercion, the Second Circuit concluded that the
 21 companies’ “hard switch crosses the line from persuasion to coercion.” *Namenda*, 787 F.3d at
 22 654.

23 By effectively withdrawing Namenda IR prior to generic entry,
 24 Defendants forced patients to switch from Namenda IR to XR – the
 25 only other memantine drug on the market. In fact, the district court
 26 found that Defendants devised the hard switch because they
 27 projected that only 30% of . . . patients would voluntarily switch to
 28 Namenda XR prior to generic entry. Defendants’ hard switch was
 expected to transition 80 to 100% of Namenda IR patients to XR
 prior to generic entry, and thereby impede generic competition.

Id.

1 Although the companies argued that no distinction should be made between the soft and
2 hard switches, the Second Circuit was not persuaded because

3 this argument ignores [a] basic tenet[]: the market can determine
4 whether one product is superior to another only “so long as the free
5 choice of consumers is preserved.” Had Defendants allowed
6 Namenda IR to remain available until generic entry, doctors and
7 Alzheimer’s patients could have decided whether the benefits of
8 switching to once-daily Namenda XR would outweigh the benefits
9 of adhering to twice-daily therapy using less-expensive generic IR
10 (or perhaps lower-priced Namenda IR). By removing Namenda IR
11 from the market prior to generic IR entry, Defendants sought to
12 deprive consumers of that choice. In this way, Defendants could
13 avoid competing against lower-cost generics based on the merits of
14 their redesigned drug by forcing Alzheimer’s patients to take XR,
15 with the knowledge that transaction costs would make the reverse
16 commute by patients from XR to generic IR highly unlikely.

17 *Id.* at 654-55.

18 The Second Circuit then held that the hard switch would likely have anticompetitive and
19 exclusionary effects.

20 Forcing patients to switch to XR would prevent generic substitution
21 because generic versions of IR are not AB-rated to Namenda XR.
22 And if, as Defendants’ own internal predictions estimate, the hard
23 switch successfully converted 80 to 100% of IR patients to XR prior
24 to generic entry, there would be “few to no prescriptions” left for
25 which generics would be eligible to compete. Because Defendants’
26 forced switch “through something other than competition on the
27 merits[] has the effect of significantly reducing usage of rivals’
28 products and hence protecting its own . . . monopoly, it is
anticompetitive.”

29 *Id.* at 655. The court acknowledged that, theoretically, Alzheimer’s patients were free to switch
30 back to IR – specifically, take a generic version once it was available. However, in practice,
31 switching back was “highly unlikely” because it would involve high transaction costs – *e.g.*, a
32 patient would have to obtain a new prescription from a doctor, but doctors and caregivers are
33 reluctant to make changes to medication if the current treatment is working. *Id.* at 656.

34 Based on *Namenda*, Gilead argues that a critical element in a switching/product hopping
35 claim is coercion. Plaintiffs disagree. They contend that this Court rejected that requirement in
36 one of its prior orders addressing a 12(b)(6) motion to dismiss. *See Opp’n at 49* (citing *Staley*, 446
37 F. Supp. 3d at 615. Plaintiffs are incorrect. In its prior decision, the Court was never squarely

1 presented with switching/product hopping authority and the issue of coercion. Thus, the Court
 2 necessarily did not express an opinion on whether coercion is required in a switching/product
 3 hopping situation. Moreover, implicit in the Court's prior order was an endorsement of the
 4 coercion element – *i.e.*, Plaintiffs' theory was that product superiority was not driving the
 5 transition from TDF to TAF but rather something else. Furthermore, a coercion element is
 6 necessarily a part of Plaintiffs' claim here because how else could there by anticompetitive
 7 conduct unless HIV patients', doctors', and/or payors' choices regarding products were
 8 constrained? *See id.* at 654-55 (noting as a basic tenet that “the market can determine whether one
 9 product is superior to another only ‘so long as the free choice of consumers is preserved’”).
 10 Finally, this case is similar to *Namenda*. As in *Namenda*, the switch to the new product impaired
 11 competition from generic manufacturers; Gilead forced patients to switch over from TDF to TAF,
 12 knowing that generics for TDF would not be AB-rated for TAF.

13 Plaintiffs suggest that coercion is not necessary where there is deceptive marketing. *See In*
 14 *re Suboxone Antitrust Litig.*, No. 2445, 2022 U.S. Dist. LEXIS 150424, at *109-10 (E.D. Pa. Aug.
 15 22, 2022) (where defendant claimed that it was safer to administer a drug in “film” form rather
 16 than tablet form, noting that “Plaintiffs have produced evidence that [defendant] actively sought to
 17 deprive consumers of the ability to actively evaluate safety claims and make the choice between
 18 film and tablets”). But here (as in *Suboxone*), the crux of the deceptive marketing relates to safety.
 19 Thus, the asserted anticompetitive element of deception in this case essentially bleeds into the
 20 larger issue of whether there was “coercion” because of safety concerns.

21 That being said, the Court does not accept all of Gilead's characterizations as to what
 22 constitutes a viable switching/product hopping claim. Most notably, Gilead suggests that there is
 23 a viable claim only where the antitrust defendant *withdraws* the old product from the market, thus
 24 forcing consumers over to the new product. Although *Namenda* did involve withdrawal of
 25 *Namenda* IR in order to drive consumers over to *Namenda* XR, that does not mean the free choice
 26 of consumers can be constrained only where the old product is withdrawn from the market.
 27 Indeed, at the hearing, Gilead acknowledged that, if a pharmaceutical company were to leave its
 28 old drug on the market but to charge an exorbitant price for it, while pricing the new drug

1 considerably less, that would effectively leave consumers or payors with little choice but to move
 2 over to the new drug. *See also In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 307, 329-30
 3 (D.R.I. 2019) (noting that “[a] hard switch may occur ‘in effect’ where the branded product
 4 remains on the market in some limited fashion”). This is not to say that withdrawal of an old
 5 product, or the continued availability of such, is of no relevance in a switching/product hopping
 6 case. The Court is simply noting here that withdrawal of an old product is not the only means of
 7 coercion. *Cf. Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Ltd. Co.*, 838 F.3d 421,
 8 4401-41 (3d Cir. 2016) (although concluding that the switching/product hopping claim asserted
 9 was not viable, indicating that “the disposition of [a] claim will necessarily turn on the facts and
 10 circumstances surrounding a company’s alleged anticompetitive conduct”).

11 Having addressed the legal framework (*i.e.*, what constitutes a plausible claim of
 12 anticompetitive switching/product hopping), the Court now turns to the facts of the instant case.
 13 Defendants contend that no reasonable jury could find a coercion element based on the undisputed
 14 facts. The Court agrees.

15 To the extent Plaintiffs assert coercion based on the pricing of Stribild, no reasonable jury
 16 could find coercion based on that evidence by itself. Plaintiffs have essentially admitted that
 17 doctors do not prescribe HIV drugs based on their price; similarly, for the most part, HIV patients
 18 do not choose their drugs based on price (largely because it is the payors, and not the consumers,
 19 who pay for the bulk of the cost). *See, e.g.*, Opp’n at 60 (stating that “[p]rice competition among
 20 branded HIV treatments is muted[;] [o]nce HIV patients are stabilized on a treatment that is
 21 working, they are likely to stay on that treatment, despite its price and changes in price”).
 22 Plaintiffs do contend that the pricing of Stribild impacted payors – *i.e.*, their formulary coverage
 23 decisions. But the question here is not whether the pricing differential *affected* formulary
 24 coverage decisions; the question is whether the pricing differential was coercive (which makes
 25 sense otherwise any rebate or discount might be deemed an antitrust violation). Even if a payor
 26 had to pay \$4,000 more per patient for Stribild over Genvoya,⁹ Plaintiffs have not explained how
 27

28 ⁹ The Court acknowledges that payors may not have paid wholesale prices but presumably
 wholesale prices give some indication of what retail prices would be.

1 that would be coercive to a payor, particularly when (1) a payor is not an individual consumer but
2 rather a business entity, and (2) it is not clear how many HIV patients are typically covered by an
3 average payor. Furthermore, Plaintiffs have not explained how, in the absence of coercion of
4 payors, there is coercion relative to HIV patients even if they are affected by payors' formulary
5 coverage decisions.

6 The critical question, therefore, is whether a reasonable jury could find coercion because
7 Gilead promoted its TAF-based drugs (*e.g.*, Genvoya) as safer compared to its TDF-based drugs
8 (*e.g.*, Stribild). The Court concludes that a reasonable jury could not so find.

9 According to Plaintiffs, Gilead was able to promote Genvoya as safer than Stribild by
10 “degrading” the safety of the latter. However, the undisputed evidence does not support the claim
11 that Stribild was degraded, let alone for anticompetitive reasons. Although Plaintiffs emphasize
12 that Gilead did not reduce the dosage of TDF in Stribild (even though a booster was included as a
13 component in the drug) and did reduce the dosage of TAF in Genvoya (which also included a
14 booster), there was a science-based reason for that difference in conduct: specifically, the
15 undisputed evidence is that TAF’s response to a booster is much stronger compared to TDF’s. *See*
16 Gant Decl., Ex. 26 (Kearney Depo. at 221, 226) (indicating that TDF is boosted by only 18%
17 while TAF is boosted by 307%). Plaintiffs argue that “even the standard *unboosted* dosage of
18 TDF was too high of an exposure for certain patients to tolerate,” Opp’n at 55 (emphasis in
19 original), but this ignores the fact that TDF was commonly used with boosters, as even Plaintiffs’
20 expert Dr. Hardy conceded. *See* Adam Reply Decl., Ex. 50 (Hardy Depo. at 217-18) (stating that
21 the package insert for Viread (TDF) cautioned that there would be increased levels of tenofovir if
22 used with a booster, but admitting that doctors commonly used TDF with a booster as part of a full
23 regimen). Moreover, the FDA has never deemed Stribild unsafe. In fact, Stribild is still listed as a
24 treatment option on the DHHS Guidelines related to HIV. *See* Adam Reply Decl., Ex. 51
25 (Follansbee Depo. at 178-80); *see also* Hardy Rpt. ¶¶ 43-44 (stating that “DHHS regularly issues a
26 set of guidelines specifically aimed at providing HIV-treatment recommendations to healthcare
27 professionals, based on the latest clinical evidence and expert opinions”; “[p]hysicians treating
28 patients with HIV rely heavily on the DHHS Guidelines because they are the best source of

1 updated, organized, curated, and reliable information”).

2 Because Stribild was not degraded (*i.e.*, as a scientific matter), it was not improper for
3 Gilead to design clinical trials comparing Stribild to Genvoya. That Gilead could have compared
4 unboosted TDF to unboosted TAF does not mean that the comparison of Stribild to Genvoya (both
5 boosted drugs) was inappropriate.

6 Moreover, it was not deceptive¹⁰ or otherwise improper for Gilead to market Genvoya as
7 being safer than Stribild, particularly given that the DHHS Guidelines indicate the same. The
8 DHHS Guidelines expressly stated that TAF-based drugs have safety benefits compared to TDF-
9 based drugs:

10 TAF/FTC was added as a 2-NRTI option in several Recommended
11 and Alternative regimens The addition of TAF/FTC to these
12 recommendations is based on data from comparative trials
13 demonstrating that TAF-containing regimens are as effective in
achieving or maintaining virologic suppression as tenofovir
disoproxil Fumarate (TDF)-containing regimens and with more
favorable effects on markers of bone and renal health.

14 Gant Decl., Ex. 47 (DHHS Guidelines at i). As noted above, DHHS issues guidelines on HIV
15 treatments, and doctors rely on those guidelines because, *inter alia*, they are reliable. According
16 to Plaintiffs’ medical expert, Dr. Hardy, the guidelines “are created by a panel of approximately 55
17 individuals, who have unique experiences and expertise derived from several different areas of
18 HIV treatment,” and the individuals “go through a rigorous confirmation process to demonstrate
19 that they have no significant conflicts of interest with pharmaceutical companies or other potential
20 influencers of this area of scientific expertise.” Hardy Rpt. ¶ 44. Before making its
21 recommendations, the panel “carefully reviews all published, peer-reviewed scientific and medical
22 information regarding antiretroviral therapy and follows a rigorous and structured grading

23

24 ¹⁰ In their papers, the parties have a dispute over whether deceive marketing is actionable for
25 antitrust purposes only when the marketing is clearly false. Plaintiffs contend that the “clearly
26 false” standard applies only where false claims are made about a competitor’s product. *See Am.*
Prof'l Testing Serv. v. Harcourt Brace Jovanovich Legal & Prof'l Publns., 108 F.3d 1147, 1152
(9th Cir. 1997) (indicating that, “[a]lthough hardly a justification for falsehood, buyer distrust of a
27 seller's disparaging comments about a rival seller should caution us against attaching much
weight to isolated examples of disparagement[;] [e]ssential, therefore, is a serious de minimis
28 test”) (emphasis added). For purposes of this opinion, the Court assumes that Plaintiffs are
correct.

1 system.” Hardy Rpt. ¶ 45; *see also* Pitrak Reb. Rpt. ¶ 53 (noting that Plaintiffs’ medical experts,
 2 Dr. Hardy and Dr. Follansbee, do not “claim that the DHHS panel was misled by any Gilead
 3 marketing or alleged misrepresentation of clinical data”). There is no indication that the DHHS
 4 was misled in any way – *e.g.*, as to the components of Stribild and Genvoya and the differences
 5 between the drugs. In fact, the components of the drugs appear to have been on the drug labels
 6 and/or in the package inserts, thus making any claim of actual falsity untenable. *See, e.g.*, Pitrak
 7 Rpt. ¶ 140 & n.84 (label for Stribild); Follansbee Rpt. ¶ 169 & n.198 (package insert for Stribild).

8 Plaintiffs protest that the benefits of TAF were limited to a small percentage of the HIV
 9 patient population (about 17%) – *i.e.*, those with acute bone or renal conditions. But Plaintiffs fail
 10 to address that HIV drugs are used for a patient’s lifetime; thus, even for a patient without an acute
 11 bone or renal condition, there are implicitly some benefits to TAF over TDF.

12 Plaintiffs also contend that the Court should not parse out the individual acts taken by
 13 Gilead – related to pricing and safety – but rather should evaluate their overall combined effect
 14 given the broad antitrust scheme pled by Plaintiffs. *See City of Anaheim v. S. Cal. Edison Co.*,
 15 955 F.2d 1373, 1376 (9th Cir. 1992) (stating that “it would not be proper to focus on specific
 16 individual acts of an accused monopolist while refusing to consider their overall combined effect”
 17 – although acknowledging that, “if all we are shown is a number of perfectly legal acts, it becomes
 18 much more difficult to find overall wrongdoing”); *cf. Suboxone*, 2022 U.S. Dist. LEXIS 150424,
 19 at *92 (stating that, “when faced with allegations of a broad antitrust scheme, it is still appropriate
 20 to consider the individual components of the scheme and whether those components could
 21 constitute anticompetitive conduct, so long as [a] court keep[s] ‘the larger scope of the scheme in
 22 context’”). While Plaintiffs make a fair point, here, the Court has considered not only the
 23 individual acts but also the acts taken collectively and still concludes that no reasonable jury could
 24 find a coercion element based on the undisputed facts.¹¹ Plaintiffs’ reliance on *Suboxone* is
 25

26
 27 ¹¹ And even if there were a genuine dispute of fact related to coercion, Plaintiffs would likely run
 28 into at least one additional obstacle. As Gilead argues, to the extent Plaintiffs seeks injunctive
 relief, there seems to be a redressability problem – *i.e.*, Plaintiffs have not shown that injunctive
 relief would address “any alleged ongoing harm” because, *e.g.*, “the pricing differential between
 TDF- and TAF-based products in 2016-17 [has] long since passed.” Mot. at 21.

1 unavailing particularly as, in that case, there was no comparable source such as the DHHS
2 Guidelines here on which doctors could rely.

3 For the foregoing reasons, the Court grants Gilead's motion for summary judgment on the
4 TAF claims – specifically, the switching/product hopping claims. As stated above, the Court's
5 ruling here does not adjudicate the issue of whether Gilead's TAF-related conduct (such as its
6 decision to delay development of the drug) will be admissible as evidence to support Plaintiffs'
7 NGR or MFE/MFEP claims.

8 **IV. MARKET POWER**

9 The Court turns next to Plaintiffs' motion for summary judgment on market power.
10 Previously, the Court certified classes with respect to following drugs: Truvada, Atripla,
11 Complera, Prezcobix, and Evotaz.¹² The Truvada and Atripla Classes (both damages classes)
12 relate to Plaintiffs' MFE/MFEP claims. The Complera Class (a damages class) and the Prezcobix
13 and Evotaz Classes (both injunctive relief classes) relate to Plaintiffs' NGR claims. Plaintiffs
14 move for summary judgment on the issue of market power for each of the five drugs.¹³

15 “Market power is the power ‘to force a purchaser to do something that he would not do in
16 a competitive market.’ It has been defined as ‘the ability of a single seller to raise price and
17 restrict output.’” *Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 464 (1992); *see also*
18 *Aya Healthcare Servs. v. AMN Healthcare, Inc.*, 9 F.4th 1102, 1112 (9th Cir. 2021) (stating that
19 “[m]arket power is the ability to raise prices above those that would be charged in a competitive
20 market”); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1111 (N.D. Cal. 2004) (noting
21 that the Federal Trade Commission Horizontal Merger Guidelines “define market power as ‘the
22 ability profitably to maintain prices above competitive levels for a significant period of time’”).

23
24 ¹² The Court also certified a cART Foundation Drug Class. However, that class is not at issue
25 here. Furthermore, given the Court's ruling above on the TAF claims, it is not clear that the cART
Foundation Drug Class has any claim remaining to pursue.

26 ¹³ In their papers, Defendants criticized Plaintiffs for (1) not identifying which specific defendant
27 had market power for a given drug and (2) not specifying the period for which the defendant had
market power. Plaintiffs, however, clarified in reply that it is the seller of a brand drug that
28 has/had market power before generic entry, and other companies are implicated because of the
allegation that there was a conspiracy to delay generic competition.

Market power may be demonstrated through either of two types of proof. One type of proof is direct evidence of the injurious exercise of market power. If the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power. The more common type of proof is circumstantial evidence pertaining to the structure of the market. To demonstrate market power circumstantially, a plaintiff must: (1) define the relevant market, (2) show that the defendant owns a dominant share of that market, and (3) show that there are significant barriers to entry and show that existing competitors lack the capacity to increase their output in the short run.

Rebel Oil Co. v. Atl. Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995) (emphasis added).

A. Direct Evidence

According to Plaintiffs, there is no genuine dispute of fact that Defendants have/had market power for the five drugs at issue based on direct evidence. As an initial matter, the Court notes that the parties have a dispute as to what constitutes direct evidence of market power. Plaintiffs assert that they need only show supracompetitive prices. Defendants argue that Plaintiffs must show both supracompetitive prices and restricted output.

The Court previously considered this issue in *Intel Corp. v. Fortress Investment Group LLC*, 511 F. Supp. 3d 1006 (N.D. Cal. 2021), noting as follows:

The Supreme Court has not clearly addressed this issue. In [*Ohio v. American Express Co.*, 138 S. Ct. 2274 (2018)], the Court noted that, if “output is expanding at the same time prices are increasing, rising prices are equally consistent with growing product demand,” but, at another point, the Court used the disjunctive, stating “[t]his Court will ‘not infer competitive injury from price and output data absent some evidence that tends to prove that output was restricted or prices were above a competitive level.’” *Id.* at 2284, 2288 (emphasis added). And although the Ninth Circuit has stated that “[e]vidence of restricted output *and* supracompetitive prices is direct evidence of market power,” *Theme Promotions, Inc. v. News America Marketing FSI*, 546 F.3d 991, 1001 (9th Cir. 2008) (added); *see also Rebel Oil v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (stating that, “[i]f the plaintiff puts forth evidence of restricted output and supracompetitive prices, that is direct proof of the injury to competition which a competitor with market power may inflict, and thus, of the actual exercise of market power”),^[14]

¹⁴ *Accord Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1476 (9th Cir. 1997) (“The plaintiffs submitted evidence that Sunrise Hospital routinely charged higher prices than other hospitals while reaping high profits. With no accompanying showing of restricted output, however, the plaintiffs have failed to present direct evidence of market power.”), *overruled in part on other grounds by Lacey*

1 the Ninth Circuit has not provided its take on the statements above
 2 in *American Express*; nor has it expressly addressed the question
 3 whether supracompetitive pricing alone can establish market power.

4 *Id.* at 1026 (emphasis in original).

5 Both parties, however, point out that, post-*American Express*, the Ninth Circuit did
 6 comment on direct evidence in *FTC v. Qualcomm Inc.*, 969 F.3d 974 (9th Cir. 2020). In
 7 *Qualcomm*, the Ninth Circuit quoted *American Express* in stating that “[d]irect evidence includes
 8 “proof of actual detrimental effects [on competition],” ‘such as reduced output, increased prices,
 9 or decreased quality in the relevant market.’” *Id.* at 989 (emphasis added). However, the Ninth
 10 Circuit then went on to state the following:

11 Allegations that conduct "has the effect of reducing consumers' choices or increasing prices to consumers do[] not sufficiently allege an injury to competition . . . [because] [b]oth effects are fully consistent with a free, competitive market." *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012) (citations omitted); *see also Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 237 (1993) ("Where . . . output is expanding at the same time prices are increasing, rising prices are equally consistent with growing product demand."). Instead, in order to prove a violation of the Sherman Act, the plaintiff must show that diminished consumer choices and increased prices are the result of a less competitive market due to either artificial restraints or predatory and exclusionary conduct. *See Am. Express*, 138 S. Ct. at 2288 ("This Court will 'not infer competitive injury from price and output data absent some evidence that tends to prove that output was restricted or prices were above a competitive level.'" (quoting *Brooke Grp. Ltd.*, 509 U.S. at 237)).

12 *Id.* at 990.

13 Arguably, *Qualcomm* still leaves some ambiguity as to what the Ninth Circuit requires for
 14 direct evidence. But there is a convincing argument that both supracompetitive prices and
 15 restricted output are necessary. As the Third Circuit has explained, it is only “[i]f a firm can
 16 profitably raise prices *without causing competing firms to expand output and drive down prices*,
 17 that firm has monopoly power,’ and therefore ‘[t]he existence of monopoly power may be proven
 18 through direct evidence of supracompetitive prices and restricted output.’” *Mylan*, 838 F.3d at
 19 434 (emphasis added). The Court also notes that, in the pharmaceutical context, there may be
 20

21 *v. Maricopa Cty.*, 693 F.3d 896 (9th Cir. 2012).

1 reasons to be cautious about finding market power based on supracompetitive pricing alone – *i.e.*,
 2 because, presumably, a brand drug will always be more expensive than a generic one, often for
 3 reasons which are not anticompetitive. *See Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38,
 4 55 (D.D.C. 2008) (noting that “[g]eneric drugs normally enter the market at a price lower than
 5 their branded equivalents” and that “[m]anufacturers of generic drugs also do not engage in the
 6 substantial marketing and promotional activities undertaken by manufacturers of branded drugs,
 7 resulting in lower costs associated with their products”; “[w]ithout a showing that Warner
 8 Chilcott’s higher prices were the result of restricted output – an inquiry that requires a showing as
 9 to the scope of the relevant market – Plaintiffs’ sources of evidence cannot unambiguously
 10 establish Warner Chilcott’s market power”). At the same time, it could be argued that, under
 11 traditional microeconomic principles, raising prices (whether by a monopolist or other competitor)
 12 would naturally tend to diminish demand (and hence output) relative to that market participant,
 13 and thus absolute categorical approach may not be appropriate. The Court need not resolve the
 14 “and/or” dichotomy at this juncture because, for the reasons discussed below, there are factual
 15 questions as to each element which preclude summary judgment.

16 1. Restricted Output

17 Defendants argue there is a genuine dispute of fact on market power because, to the extent
 18 Plaintiffs assert there is direct evidence of market power, they have failed to show that Defendants
 19 restricted output: “The reason for this is that output is increasing. For example, more than 35 new
 20 HIV products have been introduced in the market since Truvada was introduced.” Opp’n at 10.

21 In response, Plaintiffs argue that, even if they have to show restricted output, they have
 22 done so here – *i.e.*, Gilead conspired with Teva, Janssen, and/or BMS to delay generic competition
 23 and, therefore, output was restricted. *See* Reply at 28 (“[B]oth the reverse payments to Teva and
 24 the NGRs reduced output by eliminating generic manufacturers as a source of the relevant
 25 products for a period of time, thereby limiting available supply to that manufactured by the
 26 brand.”).

27 Although Plaintiffs’ theory of restricted output seems viable, the question at summary
 28 judgment is whether there is a question of fact as to restricted output. Here, there are (as discussed

1 below) disputed facts as to whether, *e.g.*, Teva or other generic manufacturers did in fact delay
 2 entry into the market as a result of the patent settlement agreement between Gilead and Teva.
 3 There are also disputed facts as to whether, even in the absence of the NGRs, Gilead, Janssen,
 4 and/or BMS would have made a “generic” version of the relevant FDC. Finally, it is debatable
 5 whether a fair assessment of output can be made in the instant case without knowing what the
 6 relevant product market is in the first place – an issue that informs the question of whether there is
 7 *indirect* evidence of market power.

8 2. Supracompetitive Pricing

9 Defendants also argue that, with respect to direct evidence of market power, there is a
 10 genuine dispute of fact on supracompetitive pricing. For the reasons discussed below, the Court
 11 agrees.

12 Plaintiffs take the position that, once a generic version of a brand drug is available, then the
 13 competitive price for the brand drug is the price of the generic; thus, the brand drug price which
 14 exceeds the generic drug price is necessarily supracompetitive. Plaintiffs’ explanation as to why
 15 the price of a generic drug is the competitive price seems to be as follows: because Defendants
 16 were (as alleged) trying to delay generic competition, “the competitive price must be the price that
 17 purchasers would have enjoyed had Defendants not taken action to prevent the entry of AB-rated
 18 generics, *i.e.*, the price of AB-rated generics.” Mot. at 62.

19 Plaintiffs’ position is problematic for several reasons. First, the authority on which
 20 Plaintiffs rely addresses a product market (not a competitive price) being defined based on the
 21 anticompetitive harm being claimed. *See Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 616
 22 (N.D. Cal. 2020) (stating that “what the appropriate product market is depends on what
 23 anticompetitive harm is being claimed”); *accord U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986
 24 F.2d 589, 598 (1st Cir. 1993) (indicating that one must “remember[] to ask, in defining the market,
 25 why we are doing so: that is, what is the antitrust question in this case that market definition aims
 26 to answer?”; adding that “the nature of the claim can affect the proper market definition”). But
 27 product market definition matters where *indirect* evidence of market power is being considered; at
 28 this juncture the focus is on *direct* evidence. Second, even if product market definition should be

1 considered for purposes of direct evidence, product market definition is only *informed* by what the
 2 alleged anticompetitive conduct is; such conduct is not automatically dispositive of the matter.¹⁵
 3 Indeed, as discussed below, product market definition typically turns on what products are
 4 economic substitutes, and there are factual questions concerning the identification of such
 5 substitutes. Finally, under Plaintiffs' position, in any generic competition case, the competitive
 6 price will be the generic price which, in turn, would seem to ““render most brand name
 7 pharmaceutical companies . . . *per se* monopolists prior to generic entry,”” *Kaiser Found. v. Abbott*
 8 *Labs.*, No. CV 02-2443-JFW (FMOx), 2009 U.S. Dist. LEXIS 107512, at *29 (C.D. Cal. Oct. 8,
 9 2009); this is a difficult proposition to embrace.

10 Plaintiffs also indicate there is direct evidence of market power based on Defendants' gross
 11 margins on their drugs – over █ “which is almost at the top of the Lerner Index range and far
 12 above the pharmaceutical industry average. The Lerner Index is the ratio of (a) the product's price
 13 minus marginal cost (or gross margin) to (b) its price, and is a common measure of market
 14 power.” Opp'n at 61; *see also In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn.
 15 2016) (stating that “[t]here are generally accepted economic means of analyzing the probability
 16 that given prices are supracompetitive using price and marginal cost” and indicating the Lerner
 17 Index is one such means). But as other courts have recognized, gross margins are not dispositive
 18 on the issue of market power. *See In re Opana ER Antitrust Litig.*, No. MDL No. 2580, 2021 U.S.
 19 Dist. LEXIS 105342, at *32 (N.D. Ill. June 4, 2021) (stating that “the Lerner index is a well-
 20 established method implemented in the field of economics to find evidence of market power,
 21 although not conclusive in and of itself”).

22 Furthermore, here, there are concrete reasons why the gross margins on the drugs at issue
 23 should not be dispositive, particularly for summary judgment purposes. First, there is evidence
 24 that Defendants' gross margins are in line with those of other pharmaceutical companies. *See Wu*
 25 Rpt. ¶ 292 (asserting that “Gilead's gross margins are not out of line with the pharmaceutical

26
 27 ¹⁵ Otherwise, an antitrust plaintiff might well have an incentive to manipulate what the relevant
 28 market is by narrowly defining what the anticompetitive conduct is. *Cf. Staley*, 446 F. Supp. 3d at
 616. (stating that “[d]efining a product market is simply a way to determine whether a defendant
 has market power”).

1 industry”). Second, there is evidence that “[m]arginal cost pricing . . . is not the applicable
 2 competitive benchmark in the pharmaceutical industry [because of] the high levels of R&D and
 3 other fixed and quasi-fixed costs.” Wu Rpt. ¶ 285; *see also United States v. Eastman Kodak Co.*,
 4 63 F.3d 95, 109 (2d Cir. 1995) (stating that “[c]ertain deviations between marginal cost and price,
 5 such as those resulting from high fixed costs, are not evidence of market power”; noting that
 6 “there was overwhelming evidence that Kodak’s film business is subject to enormous expenses
 7 that are not reflected in its short-run marginal costs” such as 8-9% of revenues being used for
 8 research and development and plants costing hundreds of millions of dollars); *In re Intuniv
 9 Antitrust Litig.*, 496 F. Supp. 3d 639, 659 (D. Mass. 2020) (stating that, “[i]n the market for a
 10 product with high fixed costs,’ such as a brand pharmaceutical product, ‘evidence that prices
 11 routinely exceed marginal costs may not necessarily be evidence that prices are supracompetitive,
 12 because even competitive prices may exceed marginal cost’[;] [a]s Judge Casper explained in
 13 *Solodyn*, treating such evidence as sufficient to establish market power would result in finding that
 14 all pharmaceutical companies exercised monopoly power”).

15 Regarding the latter, Plaintiffs contend that research and development costs are not fixed
 16 costs but rather sunk costs, and, because “[s]unk costs are one-time costs undertaken in the past
 17 and do not recur,” they “*do not have to be covered by a firm’s price to support the firm’s
 18 continued participation in the market.*” McGuire Market Power Reb. Rpt. ¶ 45 (emphasis in
 19 original); *see also Aggrenox*, 199 F. Supp. 3d at 667 (acknowledging *Kodak*’s statement that
 20 “fixed costs, rather than market power, can explain ‘certain deviations between marginal cost and
 21 price,’ but [stating] that will generally be true only if those are ongoing rather than historical fixed
 22 costs (the latter of which are sunk costs)”; “prices in a competitive market will tend . . . toward
 23 marginal cost, so prices substantially above that cost are supracompetitive by definition”); *cf. In re
 24 Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 302 n.4 (D.R.I. 2019) (stating that “[h]igh
 25 brand margins indeed may be necessary to recoup costs sunk into research and development, but
 26 the antitrust laws are not concerned with why brands need these margins, but instead how they got
 27 and, more to the point, maintained them”). While Plaintiffs’ expert, Dr. McGuire can advance this
 28 position, it is disputed by Defendants’ expert, Dr. Wu, and even some of the authority on which

1 Dr. McGuire relies seems to make statements favorable to Defendants. *See* Docket No. 1443-3
 2 (Opp'n at 48-49) (in opposition to motion to exclude Dr. Wu, pointing out that some of the
 3 academic literature cited by Dr. McGuire indicates that research and development costs do affect
 4 drug pricing). This battle of the experts cannot be resolved at summary judgment.

5 **B. Indirect Evidence**

6 Plaintiffs maintain that, even if there is a genuine dispute on market power based on direct
 7 evidence, there is no genuine dispute based on indirect evidence. As noted above, for indirect
 8 evidence of market power, “a plaintiff must: (1) define the relevant market, (2) show that the
 9 defendant owns a dominant share of that market, and (3) show that there are significant barriers to
 10 entry and show that existing competitors lack the capacity to increase their output in the short
 11 run.” *Rebel Oil*, 51 F.3d at 1434. In the instant case, Plaintiffs contend that the product market is
 12 made up of only the brand drug and its AB-rated generic and, because Defendants had 100% of
 13 the market share for a given brand drug (until there was actual generic entry), that is quintessential
 14 market power. *See* Mot. at 63.

15 As indicated above, Plaintiffs’ argument hinges on the issue of product market. A product
 16 market consists of the product at issue and all economic substitutes for that product. *See Hicks v.*
 17 *PGA Tour, Inc.*, 897 F.3d 1109, 1120 (9th Cir. 2018).

18 Economic substitutes have a “reasonable interchangeability of use”
 19 or sufficient “cross-elasticity of demand” with the relevant product.
 20 Including economic substitutes ensures that the relevant product
 21 market encompasses “the group or groups of sellers or producers
 22 who have actual or potential ability to deprive each other of
 23 significant levels of business.”

24 *Id.*; *see also* *Truck-Rail Handling Inc. v. BNSF Ry. Co.*, No. C 02-02825 JSW, 2005 U.S. Dist.
 25 LEXIS 61300, at *16 (N.D. Cal. Mar. 8, 2005) (stating that “products may be considered
 26 ‘reasonably interchangeable,’ where there is cross-elasticity of demand, *i.e.* if customers would
 27 switch to alternatives in response to a price increase in the alleged monopolist’s product”; in other
 28 words, a product market includes “‘substitute products that constrain the monopolist’s pricing”).¹⁶

¹⁶ The Ninth Circuit has also noted that a market’s boundaries “may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic

1 The Court is not persuaded that Plaintiffs are entitled to summary judgment on the issue of
 2 product market. As Defendants argue, there are questions of fact as to whether there are HIV
 3 drugs other than generics that could be economic substitutes for Defendants' brand drugs.
 4 Plaintiffs' medical experts admit that there are other drugs that can be used to treat HIV (including
 5 non-Gilead drugs), and there is evidence that some HIV patients did switch from one of
 6 Defendants' drugs to those other HIV drugs (including non-Gilead drugs), even before generic
 7 entry.¹⁷ *See, e.g.*, Toto Decl., Ex. 11 (at slide 13, noting that “[a] higher switch rate to Triumeq [a
 8 non-Gilead drug] is observed from Atripla”). There is also evidence that Gilead considered the
 9 prices of other HIV drugs in setting the pricing for its drugs. *See, e.g.*, Toto Decl., Ex. 6 (Meyers
 10 Depo. at 23-24) (testifying that Gilead “anchored our pricing to existing price points” – *e.g.*, “we
 11 anchored tenofovir to abacavir,” “FTC to 3TC,” and “elvitegravir to raltegravir”); Toto Decl., Exs.
 12 18-19 (showing similar prices for HIV regimens in 2011 and 2013). In addition, Gilead “adjusted
 13 its co-pay assistance offerings based on its competitors’ offerings.” Opp’n at 5; *see also* Toto
 14 Decl., Ex. 20 (at slide 1, assessing options for Gilead to take after competitor GSK expanded its
 15 co-pay program). In short, there is some evidence of cross-elasticity of demand. Accordingly, the
 16 Court cannot say that a reasonable jury could reach only the one conclusion favored by Plaintiffs –
 17 *i.e.*, that the product market is made up of solely the brand drug and its generic. *Cf. Mylan*, 838
 18 F.3d at 436 (rejecting plaintiff’s argument that the relevant product market consisted of the brand
 19 drug and generic; agreeing “with the District Court’s conclusion that the market was much broader
 20 and consisted of all oral tetracyclines prescribed to treat acne” because there was a consensus
 21 among dermatologists that all oral tetracyclines treat acne with similar effectiveness and “health

22
 23 entity, the product's peculiar characteristics and uses, unique production facilities, distinct
 24 customers, distinct prices, sensitivity to price changes, and specialized vendors.” *Image Tech.*
Servs. v. Eastman Kodak Co., 125 F.3d 1195, 1204 (9th Cir. 1997) (quoting *Brown Shoe Co. v.*
United States, 370 U.S. 294, 325 (1962)).

25
 26 ¹⁷ Defendants suggest that switching was driven by HIV patients moving over from older drugs to
 27 newer/more innovative/better quality drugs. The Court acknowledges that some switching seems
 28 to have been made from one Gilead drug to another Gilead drug. The Court also acknowledges
 Plaintiffs’ contention that Dr. Wu’s switching analysis for Truvada specifically is flawed because
 he excluded sales of Truvada used for PrEP purposes. Plaintiffs are free to make these points to
 the jury but, for summary judgment purposes, they are not dispositive.

1 insurers and other managed care providers encouraged the widespread substitution of numerous
2 other oral tetracyclines for Doryx"); *Intuniv*, 496 F. Supp. 3d at 663-64 (concluding that there was
3 a question of fact as to whether product market was broader in scope than just the brand drug and
4 generic; there was, *e.g.*, evidence that defendant used rebates and coupons to make the price of the
5 brand drug cheaper, which indicated that the defendant was "competing with other non-stimulant
6 ADHD treatments").

7 In response, Plaintiffs argue that, while a non-Gilead therapeutic equivalent may have
8 provided *some* restraint on the price of a given brand drug, that restraint was limited in nature, and
9 only the generic was able to constrain prices to the competitive level (*i.e.*, the generic price). *See*
10 Mot. at 65; *see also* Reply at 19 (asking “whether any price competition that Defendants faced
11 from therapeutic alternatives drove prices *to the level that generic versions of the drugs would*
12 *have delivered*”). The problem with Plaintiffs’ argument is that there are disputed questions of
13 fact as to what was/is the competitive price with respect to a given brand drug. Plaintiffs’
14 assertion turns on questions of degree, not absolutes; this implies there are question of fact.
15 Whether the generic price is *the* competitive price is hotly disputed.

16 Accordingly, the Court denies Plaintiffs' motion for summary judgment on market power.
17 Contrary to what Plaintiffs contend, there are genuine disputes of material fact on both direct
18 evidence and indirect evidence.

V. NGR CLAIMS

20 Plaintiffs assert the NGR claims against Gilead and Janssen. Both parties have moved for
21 summary judgment on the NGR claims.

22 A. Relevant Background

23 Gilead and Janssen, as well as Gilead and BMS, entered into collaboration agreements to
24 make FDCs (fixed-dose combination drugs). A FDC is, as its name suggests, made up of more
25 than one drug. For example, Truvada (a Gilead drug) is a FDC because it is made up of two
26 components: TDF and FTC. If a FDC is a *complete* HIV regimen on its own, then it is a STR
27 (single-tablet regimen). Truvada is not a STR because it is made up of two NRTIs only
28 (TDF/FTC) and needs to be taken with a third agent in order for the HIV regimen to be complete.

1 Under the collaboration agreements, Gilead and the other pharmaceutical company would
 2 each contribute one or more drugs to making a FDC.¹⁸ Because Gilead's main drugs were NRTIs
 3 and Janssen and BMS's main drugs were third agents, some of the collaboration agreements
 4 enabled the companies to offer STRs (*i.e.*, complete HIV regimens). *See* Mot. at 7. Without a
 5 collaboration agreement, a FDC would not have been possible by a *single* collaborator for several
 6 years because each collaborator's drug contribution was protected by a patent that blocked the
 7 other collaborator from offering the FDC on its own. "For example, if [Janssen] had not
 8 collaborated with Gilead on Complera [made up of Janssen's RPV and Gilead's TDF/FTC],
 9 Janssen would have had to wait until 2018 for generic 3TC[¹⁹] and generic TDF to become
 10 available, thus depriving patients of an FDC utilizing the innovative RPV component for at least
 11 seven years." Mot. at 7-8; *see also* Reply at 3.

12 Each collaboration agreement entered into by Gilead and either Janssen or BMS contains
 13 what Plaintiffs have called a NGR – *i.e.*, a noncompete provision related to generics. There are a
 14 total of five collaboration agreements at issue.²⁰

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23 ¹⁸ For some of the collaboration agreements, Gilead made financial contributions to the
 24 development of the FDC. For instance, Gilead contributed money toward the development of
 25 Symtuza. *See* Saint-Antoine Decl., Ex. 32 (Symtuza Agmt. § 9.1.2). Gilead also contributed
 26 financially to Janssen's development of RPV which was used to make Complera. *See* Mot. at 2
 (noting that "Gilead agreed to reimburse Janssen up to \$100 million for costs associated with
 developing RPV, which was in clinical trials and was two years away from FDA-approval when
 the Complera Agreement was executed"); *see also* Saint-Antoine Decl., Ex. 29 (Complera Agmt.
 § 10.1).

27 ¹⁹ 3TC is a drug that, in essence, can be used in lieu of FTC (or generic FTC).

28 ²⁰ Plaintiffs are no longer asserting a NGR claim based on the Atripla Agreement.

	Agreement	Date	Components
1	Complera Agreement (Gilead/Janssen)	July 2009	RPV TDF FTC
2	Odefsey Agreement (Gilead/Janssen)	December 2014	RPV TAF FTC
3	Prezcobix Agreement (Gilead/Janssen)	June 2011	DRV COBI
4	Syntuza Agreement (Gilead/Janssen)	December 2014	DRV TAF FTC COBI
5	Evotaz Agreement (Gilead/BMS)	October 2011	ATV COBI

12 Essentially, each NGR provided that a collaborator could not enter into competition with
 13 the collaboration drug (the FDC) by making an identical drug *or a near-identical one*. In other
 14 words, even if the first collaborator's drug used in the FDC lost its patent protection, the second
 15 collaborator could not then make a FDC consisting of its own patent-protected drug and a generic
 16 version of the first collaborator's drug. *See, e.g.*, Huttinger Decl., Ex. 85 (Summary of License
 17 and Collaboration Agreement, effective date 7/16/2009) (regarding Complera, stating that Janssen
 18 "cannot make a combination of [RPV] plus a generic version of Truvada after the patents on
 19 Truvada expire until the Agreement terminates, unless [Janssen] uses dosages therapeutically
 20 different from those in the [combination product]").

21 According to Plaintiffs, an NGR provided a way for the first collaborator to effectively get
 22 extended protection for its drug even after the patents that had protected the drug expired.

23 Defendants, in turn, argue that the NGRs were reasonably necessary in order for the
 24 collaborations to take place in the first instance and that the NGRs do not restrain any more than
 25 does an exclusive license: "For example, in terms of substantive licensing rights, . . . Janssen
 26 [could not] introduce a generic version of Complera (TDF/FTC/RPV) without practicing the RPV
 27 patents it exclusively licensed to Gilead in the field of use for Complera." Mot. at 12. Defendants
 28 also assert that the NGRs are narrow noncompetes because (1) the NGRs did not prevent a

1 collaborator from developing *different* cART drugs (including ones that would compete with the
 2 collaboration FDC), *see* Mot. at 10, and (2) the NGRs affected only the parties to the collaboration
 3 and “have no effect on third-party generic manufacturers.” Mot. at 9; *see also* Reply at 4 (arguing
 4 that the NGRs did not “impede *any* entry by generic manufacturers”; Plaintiffs’ theory “has
 5 nothing to do with the generic industry [and] is premised entirely on the wholly unsubstantiated
 6 allegation that *one of the brand collaborators* would have entered with a generic version of its
 7 own joint venture product”) (emphasis in original). With respect to (1), Janssen did in fact
 8 collaborate with other pharmaceutical companies to create FDCs to treat HIV. For example,
 9 Janssen contributed its drug RPV to make FDCs with another company known as ViiV – *e.g.*,
 10 Juluca and Cabenuva.

11 **B. Ancillary Restraint**

12 As the Court noted in a prior order, “agreements between competitors – what are known as
 13 ‘horizontal agreements’ – are suspect from an antitrust perspective.” *Staley v. Gilead Scis., Inc.*,
 14 446 F. Supp. 3d 578, 594 (N.D. Cal. 2020). But a horizontal agreement is not automatically
 15 deemed *per se* unlawful. *Cf. O’Bannon v. NCAA*, 802 F.3d 1049, 1070 (9th Cir. 2015) (stating
 16 that “[s]ome types of restraints . . . have such predictable and pernicious anticompetitive effect,
 17 and such limited potential for procompetitive benefit that they are deemed unlawful *per se*”); but
 18 “[p]er se treatment is proper only ‘[o]nce experience with a particular kind of restraint enables the
 19 [c]ourt to predict with confidence that the rule of reason will condemn it’”). Indeed, a *per se* rule
 20 does not make sense “where fusions or integrations of economic activity [between competitors]
 21 occur[]” and the competitors agree to a restraint simply to “eliminate[] rivalry within [their]
 22 enterprise [as a] means of enhancing the [enterprise’s] efficiency.” *Rothery Storage & Van Co. v.*
 23 *Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986); *see also* Areeda & Hovenkamp,
 24 Antitrust Law ¶ 2134 (noting that, “[w]hen the noncompetition agreement is . . . an agreement
 25 creating a new business, the offsetting benefits can be significant”). The ancillary restraints
 26 doctrine recognizes this principle.

27 Under the “ancillary restraints” doctrine, a horizontal agreement is
 28 “exempt from the *per se* rule,” and analyzed under the rule-of-reason
 [instead], if it meets two requirements. These requirements are that

1 the restraint must be (1) "subordinate and collateral to a separate,
 2 legitimate transaction," and (2) "reasonably necessary" to achieving
 3 that transaction's pro-competitive purpose.
 4

5 *Aya Healthcare Servs. v. AMN Healthcare, Inc.*, 9 F.4th 1102, 1109 (9th Cir. 2022); *see also*
 6 Areeda & Hovenkamp, Antitrust Law ¶ 1905 (stating that "[a] restraint is ancillary if it somehow
 7 makes the market more competitive by facilitating the creation of a new product or process,
 8 enabling new entry, or expanding output").

9 According to Gilead/Janssen, the NGRs are ancillary restraints and therefore subject to the
 10 rule of reason. Gilead/Janssen also argue that, under a rule-of-reason analysis, they are entitled to
 11 summary judgment. Plaintiffs have not moved on summary judgment based on the rule of reason.
 12 Rather, Plaintiffs contend that quick look review, instead of the rule of reason, should apply. *See*
 13 *Cal. ex rel. Harris*, 651 F.3d 1118, 1134 (9th Cir. 2011) (noting that "the rule of reason analysis
 14 can sometimes be applied 'in the twinkling of an eye'"; "this truncated rule of reason or 'quick
 15 look' antitrust analysis may be appropriately used where 'an observer with even a rudimentary
 16 understanding of economics could conclude that the arrangements in question would have an
 17 anticompetitive effect on customers and markets'"). Plaintiffs assert that, under the quick look
 18 standard, they are entitled to summary judgment.

19 As an initial matter, the Court notes that the Ninth Circuit has not clearly articulated how
 20 quick look review applies when analyzing ancillary restraints. As noted above, in *Aya* (and in
 21 other cases), the Ninth Circuit has discussed the ancillary restraints doctrine in terms of the per se
 22 rule and rule-of-reason standard only. *See, e.g.*, *Aydin Corp. v. Loral Corp.*, 718 F.2d 897, 901
 23 (9th Cir. 1983) (stating that "[t]he proper function of ancillarity in the antitrust analysis 'is to
 24 remove [in some instances] the per se label from restraints otherwise falling within the category'[,]
 25 [w]hether a restraint that does not fall within a per se category is ancillary to a valid agreement is
 26 relevant only in the sense that ancillarity increases the probability that the restraint will be found
 27 reasonable"). The Seventh Circuit, however, has indicated that an ancillary restraints analysis is,
 28 in some respects, a quick look review in and of itself, *i.e.*, to determine whether a full-blown rule-of-reason analysis is warranted:

A court must distinguish between "naked" restraints, those in which

1 the restriction on competition is unaccompanied by new production
 2 or products, and “ancillary” restraints, those that are part of a larger
 3 endeavor whose success they promote. . . .

4

5 A court must ask whether an agreement [not to compete] promoted
 6 enterprise and productivity at the time it was adopted. If it *arguably*
 7 did, then the court must apply the Rule of Reason to make a more
 8 discriminating assessment. . . .

9 A restraint is ancillary when it *may* contribute to the success of a
 10 cooperative venture that promises greater productivity and output.
 11 If the restraint, viewed at the time it was adopted, *may* promote the
 12 success of this more extensive cooperation, then the court must
 13 scrutinize things carefully under the Rule of Reason. Only when a
 14 quick look reveals that “the practice facially appears to be one that
 15 would always or almost always tend to restrict competition and
 16 decrease output” should a court cut off further inquiry.

17 *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 188-89 (7th Cir. 1985) (emphasis
 18 added); *see also* Areeda & Hovenkamp, Antitrust Law ¶ 1908 (stating that “[d]etermining whether
 19 a restraint is ancillary is simply a way of deciding whether it can be condemned as illegal ‘per se,’
 or upon a relatively quick look; or whether a more complete analysis of the market and likely
 competitive effects is essential”); *cf. MLB Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 338 (2d Cir.
 20 2008) (Sotomayor, J., concurring) (stating that “a *per se* or quick-look approach may apply to [a]
 21 joint venture[] . . . where a particular challenged restraint is not reasonably necessary to achieve
 22 any of the efficiency-enhancing benefits of a joint venture and serves only as [a] naked restraint
 23 against competition”).

24 Notably, in its most recent case on the ancillary restraints doctrine, the Ninth Circuit quoted
 25 *Polk* with approval: ““A restraint is ancillary when it *may* contribute to the success of a
 26 cooperative venture that promises greater productivity and output.”” *Aya*, 9 F.4th at 1110
 27 (emphasis added). Accordingly, even though the Ninth Circuit has stated that a restraint is
 28 ancillary only if, *inter alia*, it is ““reasonably necessary’ to achieving [the] transaction’s pro-
 competitive purpose,” *id.* at 1109, the “reasonably necessary” requirement does not demand as
 much rigor as the language might suggest. *See also Med. Ctr. at Elizabeth Place, LLC v. Atrium
 Health Sys.*, 922 F.3d 713, 726 (6th Cir. 2019) (rejecting the contention that “an ancillary restraint
 must be *necessary* to achieve the joint venture’s efficiency-enhancing purpose”; so long as a

1 restraint *arguably* or *plausibly* promotes enterprise and productivity, that is sufficient to warrant
 2 application of the rule of reason) (emphasis in original); *cf. Aya*, 9 F.4th at 1111 (stating that a
 3 defendant “need not satisfy a less-restrictive-means test to demonstrate that the [restraint] is an
 4 ancillary [one]”; “the less restrictive alternative analysis falls within the rule-of-reason analysis,
 5 not the ancillary restraint consideration.”). Indeed, in *Aya*, the Ninth Circuit concluded that a
 6 restraint was reasonably necessary because, without it, the defendant ““would *likely* be less willing
 7 or unwilling” to enter into the parties’ cooperative agreement.²¹ *Aya*, 9 F.4th at 1109 (emphasis
 8 added).

9 The Court thus follows the approach expressly taken by the Seventh Circuit – and
 10 implicitly followed by the Ninth Circuit – in evaluating whether the NGRs are ancillary
 11

12
 13 ²¹ In *Aya*, the plaintiff and defendant were both healthcare staffing agencies that placed travel
 14 nurses on temporary assignment. *See Aya*, 9 F.4th at 1106. Because the defendant was unable to
 15 fill the demand of its hospital customers for travel nurse assignments, it began to refer “spillover
 16 assignments” to its network of subcontractors (other healthcare staffing agencies). The plaintiff
 17 and defendant entered into a subcontracting agreement, and that agreement contained a provision
 18 that prohibited the plaintiff from soliciting the defendant’s employees. The defendant terminated
 19 its relationship with the plaintiff after the plaintiff began to actively solicit the defendant’s travel
 20 nurse recruiters. *See id.* at 1106-07. The plaintiff then sued the defendant, arguing that the
 21 nonsolicitation agreement was an antitrust violation. The Ninth Circuit recognized that the
 22 parties’ nonsolicitation agreement was a horizontal restraint because, even though “the parties
 23 were ‘in a subcontractor-subcontractee relationship,’ the agreement ‘restricts [the defendant’s]
 24 actual or potential employer-rival . . . from competing with [the defendant] for its employees by
 25 soliciting them to work for [the plaintiff].’” *Id.* at 1109. But the Ninth Circuit held that the
 26 nonsolicitation agreement was

27 reasonably necessary to the parties’ pro-competitive collaboration. The purpose of the parties’ contract was to supply hospitals with traveling nurses. The non-solicitation agreement is necessary to achieving that end because it ensures that [the defendant] will not lose its personnel during the collaboration. As the district court noted, [the defendant] may want to “guard[] its investments and establish[] . . . relationships with only those agencies that agree, *inter alia*, not to abuse the relationship by proactively raiding [the defendant’s] employees, [associate vendors], and customers.” Without the restraint, [the defendant] “would likely be less willing or unwilling to deal with other agencies to supply travel nurses to hospitals which, as [the plaintiff] also recognize[d], already experience a ‘chronic shortage of nurses.’” And with the restraint, [the defendant] may collaborate with its competitor for the benefit of its client without “cutting [its] own throat.”

28 *Id.* at 1110.

1 restraints.²² Notably, the ancillary restraints issue appears to be one for the Court, and not a jury,
 2 to decide. *See Staley*, 446 F. Supp. 3d at 596 (noting that “the decision of what mode of analysis
 3 to apply . . . is entirely a question of law for the Court,’ although that legal question ‘might involve
 4 factual disputes’”); *cf. Med. Ctr. at Elizabeth Place, LLC v. Atrium Health Sys.*, 922 F.3d 713, 727
 5 (6th Cir. 2019) (stating that “whether a given restraint falls within the *per se* category is a question
 6 of law”). The Court analyzes the issue here using this framework.

7 In the instant case, there is no real dispute that the NGRs are “subordinate and collateral to
 8 a separate, legitimate transaction” (i.e., the collaboration agreements). *Id.* at 1109; *see also*
 9 Opp’n at 31 (acknowledging that “introducing new FDCs increases consumer choice and
 10 combining HIV drugs reduces pill burden and may increase adherence and improve treatment
 11 outcomes”). Plaintiffs’ main contention is that the NGRs were not reasonably necessary in order
 12 for the collaborations to have taken place in the first instance. According to Plaintiffs, the NGRs
 13 are inherently suspect because they effectively give protection to a collaborator’s drug even after
 14 the patent protecting the drug has expired. Plaintiffs also argue that the NGRs were not
 15 reasonably necessary for the collaborations because the collaboration agreements would have been
 16 profitable for Gilead and Janssen, or Gilead and BMS, even if no NGRs were included. In other
 17 words, because significant profits could still be made, Plaintiffs assert that the companies would
 18 have entered into the collaborations even without any NGRs. Finally, Plaintiffs contend that
 19 Gilead/Janssen’s justifications for the NGRs – preventing a collaborator from free riding on the
 20 efforts of the joint venture and protecting each collaborator’s know-how – are not cognizable
 21 and/or not plausible.

22 Although Plaintiffs’ arguments above are not without any merit, they cannot prevail as a

23
 24 ²² In their papers, Plaintiffs have cited the Seventh Circuit’s decision in *Polk* approvingly.
 25 Although Plaintiffs’ initial interpretation of *Polk* was not entirely consistent with the Court’s
 26 interpretation above, *see* Opp’n at 30 (arguing that, under *Polk*, “even if the Court finds the NGRs
 27 to be ancillary restraints, they still must be scrutinized using the quick look approach or evaluated,
 28 at a minimum, under a full-blown rule of reason analysis”), their subsequent interpretation, as
 articulated in their sur-reply, is. *See* Sur-Reply at 10 (stating that both the quick look doctrine and
 the ancillary restraints “serve as screening tools that allow the Court to determine the appropriate
 mode of analysis without a full-blown economic assessment of market power and effects”); *cf.*
 Sur-Reply at 18 (conceding that the Ninth Circuit’s decision in “*Aya* can be interpreted to adopt a
 plausibility standard with respect to the ancillary restraints doctrine”).

1 matter of law. First, while Plaintiffs correctly note that “all patents, and all benefits from them,
2 must end when their terms expire,” *Kimble v. Marvel Entm’t, LLC*, 576 U.S. 446, 463 (2015), that
3 is simply a reflection of patent law. What transgresses patent law is not necessarily equivalent to
4 what transgresses antitrust law. In *Kimble*, the Supreme Court held that the payment of royalties
5 after patent expiration was unlawful as a matter of patent law only, not antitrust law. *See id.* at
6 462-63 (noting that precedent “did not rely on the notion that post-patent royalties harm
7 competition”; “in deciding whether post-expiration royalties comport with patent law, *Brulotte* did
8 not undertake to assess that practice’s likely competitive effects” but rather “applied a categorical
9 principle that all patents, and all benefits from them, must end when their terms expire.”).
10 Therefore, conduct that protects a product after patent expiration is not automatically an antitrust
11 violation, nor is it inherently suspect (though it may be taken into account as part of the antitrust
12 calculus).

13 Second, there is no dispute that the collaborations in and of themselves are procompetitive,
14 making new products available and earlier in time (*i.e.*, compared to when products using generic
15 components would be available). And as Defendants argue, the NGRs plausibly facilitated those
16 collaborations, and made it more likely that Gilead and Janssen, or Gilead and BMS, would enter
17 into the collaborations in the first place. The brand manufacturers were more likely to enter into
18 collaborations with the NGRs because the NGRs prevented a collaborator from competing with
19 the collaboration by selling, an identical or near identical drug. *See Princo Corp. v. ITC*, 616 F.3d
20 1318, 1336 (Fed. Cir. 2010) (stating that “‘ancillary restraints’ that are often important to
21 collaborative ventures [include] agreements between the collaborators not to compete against their
22 joint venture”); *Engine Specialties, Inc. v. Bombardier, Ltd.*, 605 F.2d 1, 11 (1st Cir. 1979)
23 (stating that a certain provision was “not offensive in and of itself” because it simply stated that
24 “neither of the parties to the joint venture will compete with it by acting as agents for other
25 parties”); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 280 (6th Cir. 1898) (Taft, J.)
26 (noting that, “when two men became partners in a business, although their union might reduce
27 competition, this effect was only an incident to the main purpose of a union of their capital,
28 enterprise, and energy to carry on a successful business, and one useful to the community[;]

1 [r]estrictions in the articles of partnership upon the business activity of the members, with a view
 2 of securing their entire effort in the common enterprise, were, of course, only ancillary to the main
 3 end of the union, and were to be encouraged"). Even if, as Plaintiffs contend, significant profits
 4 could have been made from collaborations without any NGRs, it is plausible that the brand
 5 manufacturers were less willing to collaborate without them.

6 Furthermore, the NGRs may have facilitated the collaborations in other ways – because, as
 7 Defendants contend, they arguably prevented a collaborator from free riding on the efforts of the
 8 joint venture and/or protected each collaborator's know-how. Courts and other authorities have
 9 recognized that free riding is a legitimate concern when people or entities embark on a joint
 10 venture. *See, e.g., Rothery*, 792 F.2d at 217, 221 (national moving company, Atlas, required that
 11 any independent moving company doing business as its agent either (1) "abandon its independent
 12 interstate authority and operate only under Atlas' authority" or (2) "create a new corporation . . . to
 13 conduct interstate carriage separate from its operation as an Atlas agent"; concluding that "the
 14 challenged agreement enhances the efficiency of the van line" by eliminating "the problem of the
 15 free ride": "[t]o the degree that a carrier agent uses Atlas' reputation, equipment, facilities, and
 16 services in conducting business for its own profit, the agent enjoys a free ride at Atlas' expense");
 17 *Med. Ctr. at Elizabeth Place*, 922 F.3d at 730 (defendant-hospitals contracted with physicians and
 18 payers on the condition that they not do business with plaintiff-hospital; stating that "Hospital
 19 Defendants had a plausible concern that, without these contracts, physicians who invested in
 20 [plaintiff] could rent office space at a [defendant]-associated hospital, free ride on the reputation
 21 and facilities of that hospital, and then refer patients out to [plaintiff]"); *Aya*, 9 F.4th at 1110
 22 (defendant-health care staffing agency hired plaintiff-health care staffing agency as a
 23 subcontractor and included a nonsolicitation provision in their contract; finding that restraint
 24 reasonably necessary because "it ensures that [defendant] will not lose its personnel during the
 25 collaboration": defendant "may want to 'guard[] its investments and establish[] [subcontracting]
 26 relationships with only those agencies that agree, *inter alia*, not to abuse the relationship by
 27 proactively raiding [defendant's] employees, [associate vendors], and customers'"); *see also*
 28 Areeda & Hovenkamp, Antitrust Law ¶ 2213c (stating that "joint venturers may have quite

1 legitimate reasons for restraining members' competitive business outside the venture," with
 2 "[m]ost such concerns apply[ing] to some variation of the free rider problem[;]" [b]asically, the
 3 venture must have some way of protecting the intellectual property, trade secrets and other
 4 learning of the venture from being used in competition with the venture itself," and, "[i]f such
 5 protection is insufficient the venture will be deterred from forming in the first place").

6 In the case at bar, the brand manufacturers had a plausible concern that there could be free
 7 riding on their joint ventures – *i.e.*, one collaborator could piggyback on the time, effort, and
 8 expense/investment put into the joint venture FDC and offer its own competing FDC once generic
 9 components were available (that it could combine with its own brand component). *See, e.g.*,
 10 Saint-Antoine Decl., Ex. 7 (Gilead/O'Connell Depo. at 305-06) (referring to "the investments
 11 Gilead would need to make financially and in resources and time in developing R/F/TAF being
 12 subverted by our partner on that drug developing a direct competitor containing those
 13 components"); Saint-Antoine Decl., Ex. 38 (Gilead/O'Connell email) (stating that "[t]he mutual
 14 non-compete remains an important issue to Gilead senior management" as "[i]t would be
 15 untenable for our partner to develop a DRV combo containing TDF while Gilead is investing in
 16 development of the STR"); Huttinger Decl., Ex. 101 (Gilead/O'Connell email) (stating that, "[i]n
 17 my view, this [NGR] would be a nice 'get' and is justified as a way to encourage the parties to
 18 commit exclusively to investing in this new improved product[;]" [w]e clearly don't want our
 19 investments in R/F/TAF to be wasted by one party developing a direct competitor"); Saint-
 20 Antoine Decl., Ex. 27 (Janssen/Stoffels email) (stating that "[w]e need to be sure, we have
 21 exclusivity to the DRV-COBI combo to avoid generic entrance including by [Gilead]
 22 themselves").

23 Plaintiffs correctly note that generic piggybacking is authorized and/or encouraged by
 24 federal law: for example, the Hatch-Waxman Act expressly allows a generic manufacturer to file
 25 an abbreviated new drug application instead of a new drug application. *See FTC v. Actavis, Inc.*,
 26 570 U.S. 136, 142 (2013) (noting that "[t]he Hatch-Waxman Act permits a generic manufacturer
 27 to file an Abbreviated New Drug Application [instead of a New Drug Application] specifying that
 28 the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-

1 approved brand-name drug” – thus allowing a generic manufacturer “to piggyback on the [brand
2 drug] pioneer’s approval efforts”). And clearly, generic piggybacking can happen without any
3 collaboration. But contrary to what Plaintiffs suggest, this does not necessarily mean that joint
4 venture efforts would not be of any value to a collaborator wanting to make a competing FDC
5 with its own brand component plus generic components. Arguably, joint venture efforts in which,
6 *e.g.*, technical information is shared and made available, would make it easier for the company to
7 make its own competing FDC. And the enhanced risk of that piggybacking via the joint venture
8 could likely make the other collaborator less willing to enter into the collaboration.

9 The NGRs also made Gilead, Janssen, and/or BMS more likely to collaborate because they
10 plausibly provided protection for the companies’ know-how – including that related to “clinical
11 development, regulatory approval, and manufacturing of each FDC.”²³ Mot. at 21. *See, e.g.*,
12 Saint-Antoine Decl., Ex. 6 (Gilead/Meyer Depo. at 73-74) (testifying that, “[b]y 2014 we had
13 essentially handed over the keys to the shop, if you will, to Janssen,” including proprietary
14 “[i]nformation around how we scaled up manufacturing, our regulatory filing processes, our co-
15 formulation capabilities and techniques”); Saint-Antoine Decl., Ex. 2 (Janssen/Watson Depo. at
16 104-05) (testifying that Gilead was getting “unique insight . . . into the way that we would develop
17 [the drug] and how we would manufacture it”; “we were also investing heavily in the development
18 program and working together, by the way, on that development program, which is every different
19 from taking an exclusive license, paying an upfront in milestones and the partners never doing
20 anything together”); Saint-Antoine Decl., Ex. 2 (Janssen/Watson Depo. at 95-96) (stating that “we
21 were sharing our development strategy and plans[;] [s]o the fact that they can comment on our
22 protocols, they were seeing, way ahead of the rest of the market, what we planned to do in terms
23 of studying this asset and putting, you know, the plans together to develop the fixed-dose
24 combination” – “[s]o now they have a distinct advantage by seeing our clinical strategy and our

25
26 ²³ To the extent Plaintiffs point out that the collaboration agreements already included
27 confidentiality provisions that protected know-how, that is an argument that there was a less
28 restrictive alternative available – which is part of a rule-of-reason analysis. Moreover, Defendants
have raised plausible arguments that confidentiality provisions have limitations (*e.g.*, it is likely
easier to prove a violation of a noncompete clause as opposed to a confidentiality clause) and that
noncompete provisions thereby give added assurances to collaborators.

1 clinical expertise that went into that plan” and “there would have to be certain manufacturing
 2 information shared between the parties [too]”); Saint-Antoine Reply Decl., Ex. 73
 3 (Gilead/O’Connell Depo. at 107-08) (testifying that Janssen would give Gilead, *e.g.*, “safety
 4 reports on darunavir [component used in Prezcobix and Symtuza],” “regulatory filings,”
 5 “proprietary data that goes into those regulatory filings,” “technique, manufacturing secrets,” and
 6 “process development secrets”); Saint-Antoine Reply Decl., Ex. 75 (Janssen and Gilead
 7 exchanging draft summaries of “Biopharmaceutical Studies and Associated Analytical Methods”
 8 regarding Complera); Saint-Antoine Reply Decl., Ex. 76 (in slides related to Symtuza meeting,
 9 indicating that Gilead/Janssen discussed Janssen’s proposed “Development Plan” and “Clinical
 10 Studies” and that Gilead provided “Clinical Trial Materials” Gilead to provide “Clinical Trial
 11 Materials” on COBI, FTC, and TAF); Saint-Antoine Reply Decl., Ex. 77 (in minutes related to
 12 Prezcobix, indicating that Gilead would conduct clinical studies evaluating whether COBI
 13 “adequately boosts . . . DRV”).

14 To be clear, this is not to say that the NGRs thereby withstand antitrust scrutiny. The
 15 Court’s only conclusion here is that, because the NGRs *may* have facilitated the collaborations,
 16 they fall within the ancillary restraint rubric and therefore a more searching analysis under the rule
 17 of reason must be done.

18 Accordingly, the Court holds that there is a sufficient showing that the NGRs are ancillary
 19 restraints. The NGRs arguably facilitate the procompetitive collaborations in several ways:
 20 because they plausibly prevent a collaborator from competing with the collaboration with an
 21 identical or near identical drug; prevent a collaborator from free riding on the joint venture efforts;
 22 and protect a collaborator’s know-how. The rule of reason therefore applies.²⁴

23

24 Even if Plaintiffs are correct that the Court should do a quick-look review *after* finding the
 25 NGRs to be ancillary restraints, they would fare no better. “[Q]uick-look analysis carries the day
 26 when the great likelihood of anticompetitive effects can easily be ascertained,” *i.e.*, “where a
 27 practice has obvious anticompetitive effects” or where there are not even any “plausibl[e]”
 28 procompetitive effects. *Cal. Dental Ass’n v. F.T.C.*, 526 U.S. 756, 770 (1999). Here, it is hard to
 say that anticompetitive effects are obvious if only because whether there are anticompetitive
 effects will turn in part on what the product market is. *See Worldwide Basketball & Sport Tours,
 Inc. v. NCAA*, 388 F.3d 955, 961 (6th Cir. 2004) (“Under the ‘quick-look’ approach, extensive
 market and cross-elasticity analysis is not necessarily required, but where, as here, the precise
 product market is neither obvious nor undisputed, the failure to account for market alternatives

1 At the hearing, Plaintiffs argued that, at the very least, the expanded NGR for Complera
 2 should not be considered an ancillary restraint and should instead be subject to quick look review.
 3 The NGR in the original Complera Agreement from 2009 precluded a collaborator from
 4 competing with generic versions of the component drugs only (RPV/TDF/FTC). In 2014, when
 5 the parties entered into the Odefsey Agreement (Odefsey being the “successor” drug to Complera
 6 but using TAF instead of TDF), the parties also agreed to broaden the NGR for Complera – *i.e.*, so
 7 that a collaborator was precluded from using not only generic FTC but also 3TC (a substitute drug
 8 for FTC). Plaintiffs contend that Janssen agreed to the broadening of the Complera NGR only
 9 when Gilead agreed to provide a reciprocal benefit to Janssen, *i.e.*, including a NGR in the
 10 Symtuza Agreement that would run to the benefit of Janssen. *See* Opp’n at 29. In short, the
 11 companies exchanged non-compete provisions (a broadened one for Gilead).

12 Although Plaintiffs may have a better argument here, the Court is not persuaded that the
 13 rule of reason should therefore be bypassed. As noted in one learned antitrust treatise:

14 An agreement between two established stores in a shopping center
 15 that divides the products they will sell and unaccompanied by any
 16 new integration or enterprise[] is . . . viewed with great suspicion.
 17 However, they may be justified nonetheless if they accompany
 18 secondary transactions that continue or expand the previously
 19 existing joint venture or business relationship[:]. For example, firms
 20 may already have developed a venture to engage in research and
 21 development of a product but negotiate a noncompetition agreement
 22 later, when they have succeeded and marketing is contemplated. *Or*
 23 *[firms] may have an established venture covering the development*
 24 *of a product but contemplate expansion of sales or development of a*
 25 *second product.*

26 Areeda & Hovenkamp, Antitrust Law ¶ 2134d2 (emphasis omitted and added). Here, there was
 27 such an established venture and Plaintiffs have not demonstrated there was no business
 28 justification (such as contemplated expansion of sales or development of a second product) for the
 expansion of the NGR. *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005), the main

26 and to analyze the dynamics of consumer choice simply will not suffice.”); *Deutscher Tennis*
 27 *Bund v. ATP Tour, Inc.*, 610 F.3d 820, 832 (3d Cir. 2010) (“Because ‘the contours of the market’
 28 here are not ‘sufficiently well known or defined to permit the court to ascertain without the aid of
 extensive market analysis whether the challenged practice impairs competition,’ ‘quick look’ is
 not appropriate and proof of relevant market is required under full-scale rule of reason.”).

1 authority cited by Plaintiffs at the hearing, is not to the contrary. In *Polygram*, two companies
 2 agreed to distribute together a recording of a concert given by the Three Tenors in 1998. They
 3 then agreed to suspend, for a period of time, advertising and discounting of two different concert
 4 albums by the Three Tenors, one distributed by one company in 1990 and the other distributed by
 5 the other company in 1994. The D.C. Circuit noted that “[a]n agreement between joint venturers
 6 to restrain price cutting and advertising with respect to products *not* part of the joint venture looks
 7 suspiciously like a naked price fixing agreement between competitors.” *Id.* at 37 (emphasis
 8 added). But *Polygram* differs from the instant case because, there, the earlier products were not
 9 part of any joint venture between the companies. Here, the opposite is true.

10 Because the Court concludes that the NGRs are ancillary restraints, the rule of reason
 11 applies, and Plaintiffs’ motion for summary judgment (which is dependent on a quick look review)
 12 is denied.

13 C. Rule of Reason

14 Under the rule of reason,

15 the plaintiff has the initial burden to prove that the challenged
 16 restraint has a substantial anticompetitive effect that harms
 17 consumers in the relevant market. If the plaintiff carries its burden,
 18 then the burden shifts to the defendant to show a procompetitive
 19 rationale for the restraint. If the defendant makes this showing, then
 the burden shifts back to the plaintiff to demonstrate that the
 procompetitive efficiencies could be reasonably achieved through
 less anticompetitive means.

20 *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018).

21 As noted above, Defendants contend that, under the rule of reason, they are entitled to
 22 summary judgment on Plaintiffs’ NGR claims. The Court rejects the bulk of Defendants’ motion.
 23 There are multiple disputes of fact that cannot be resolved at this juncture of the proceedings: for
 24 example: what is the proper product market (discussed in Part IV, *supra*); whether a collaborator
 25 would in the but-for world (*i.e.*, a world with no NGR), sell a competing FDC once a generic
 26 component(s) became available; whether the NGRs prevent free riding or protect know-how; and
 27 whether there are alternatives less restrictive than the NGRs (*e.g.*, a confidentiality provision).

28 The only issue that gives the Court pause is Defendants’ contention that Plaintiffs have

1 failed to show substantial anticompetitive effects with respect to the Prezcobix, Odefsey, and
2 Symtuza Agreements. The following is undisputed with respect to these drugs.

- 3 • Prezcobix = DRV/COBI. DRV currently has patents and regulatory exclusivity
4 that would block Gilead from entering with a “generic” version of Prezcobix until
5 2026. COBI has patents that would block Janssen from entering with a “generic”
6 version of Prezcobix until 2032.
- 7 • Odefsey = RPV/TAF/FTC. Although a generic version of FTC is now available,
8 TAF has patents and regulatory exclusivity that would block Janssen from entering
9 with a “generic” version of Odefsey until 2033. RPV has patents that would block
10 Gilead from entering with the “generic” version of Odefsey until 2025.
- 11 • Symtuza = DRV/TAF/FTC/COBI. As noted above, although a generic version of
12 FTC is now available, TAF has patents and regulatory exclusivity that would block
13 Janssen from entering with a “generic” version of Symtuza until 2033 (and COBI
14 patents would also be a block until 2032). DRV currently has patents and
15 regulatory exclusivity that would block Gilead from entering with a “generic”
16 version of Symtuza until 2026.

17 Because of the patents and regulatory exclusivities, Defendants argue that Plaintiffs cannot
18 show anticompetitive effects as a result of the NGRs; in other words, it is (at least currently) the
19 patents and regulatory exclusivities that bar competition, not the NGRs. *See also* Mot. at 15
20 (asserting that, even if there were no NGRs, “neither of the collaborators can enter with generic
21 versions of these three FDCs for the simple reason that their respective components are . . .
22 protected, and they will be for years”). Defendants add that “any contention by Plaintiffs that they
23 might suffer harm after these blocking patents begin to expire at the earliest in 2025 is pure
24 speculation and insufficient to confer antitrust standing. The intense pace of innovation in HIV
25 treatment makes any claim of future harm even more implausible.” Mot. at 15.

26 As indicated by the above, Defendants’ position is effectively a challenge to Plaintiffs’
27 standing. In response, Plaintiffs argue that the Court already rejected Defendants’ standing
28 argument in its class certification order. While Plaintiffs’ position is not without any basis, the

1 relevant part of the class certification order reflects that the Court’s focus at that time was
 2 redressability. Here, Defendants are focusing on whether there is a sufficient threat of injury in
 3 fact for purposes of standing. *See* Docket No. 56 (Order at 56) (“Defendants contend that the
 4 EPPs lack standing to seek this injunctive relief [barring enforcement of the NGRs in the Evotaz
 5 and Prezcobix Agreements] because of a redressability problem – *i.e.*, a decision favorable to the
 6 EPPs would not likely redress the injury asserted. According to Defendants, this is because there
 7 is no indication that ‘an injunction would result in Gilead selling generic-based versions of [the
 8 drugs]’”).

9 Although the collaboration agreements at issue presently contain allegedly illegal
 10 provisions (the NGRs), Plaintiffs have not demonstrated that they are suffering any injury *now* and
 11 therefore Plaintiffs’ standing is predicated on a future injury. “A plaintiff threatened with future
 12 injury has standing to sue if the threatened injury is *certainly impending*, or there is a *substantial*
 13 *risk that the harm will occur.*”²⁵ *McGee v. S-L Snacks Nat’l*, 982 F.3d 700, 709 (9th Cir. 2020)
 14 (emphasis added). Here, the Court cannot say that the threatened injury from the NGRs is
 15 certainly impending because patents and regulatory exclusivities block generic versions of the
 16 drugs at issue for several, if not many, years. It is not clear that there is a substantial risk of future
 17 harm because generics for the drugs will not be available for years and – as Defendants point out –
 18 potentially, the drugs at issue will effectively be obsolete when generics can be made given the
 19 pace of innovation in the HIV drug arena. *See* Jena Rpt., Ex. 1 (listing FDA-approved drugs for
 20 the treatment of HIV over the years, from 1987 to 2022).

21 Accordingly, the Court largely denies Defendants’ motion for summary judgment on the
 22 NGR claims, but grants it as to Prezcobix, Odefsey, and Symtuza based on lack of standing for
 23 injunctive and declaratory relief. This means that Plaintiffs’ NGR claims are limited to Complera
 24 and Evotaz.

25 A likelihood of future injury is required whether the relief sought is injunctive relief or declaratory relief. *See Hodgers-Durkin v. De La Vina*, 199 F.3d 1037, 1044 (9th Cir. 1999) (“The named plaintiffs’ failure to establish a likelihood of future injury similarly renders their claim for declaratory relief unripe.”).

1

VI. MFE/MFEP CLAIMS

2 Finally, Plaintiffs assert the MFE/MFEP claims against Gilead and/or Teva. Gilead and
 3 Teva have moved for summary judgment on the MFE/MFEP claims.

4 Originally, Plaintiffs had claims based on two different settlement agreements entered into
 5 by Gilead/Teva: a 2013 agreement related to TDF (the “TDF Patent Settlement Agreement”) and a
 6 2014 agreement related to FTC (the “FTC Patent Settlement Agreement”). Plaintiffs are no longer
 7 moving forward with any claim based on the TDF Patent Settlement Agreement and instead are
 8 asserting claims based on the FTC Patent Settlement Agreement only.²⁶

9 A. Relevant Background

10 Gilead launched Viread (TDF) in 2001; Truvada (FTC/TDF) in 2004; and Atripla
 11 (TDF/FTC/EFV) in 2006. *See* Defs.’ Appx. at 1; McGuire Rpt. ¶¶ 16, 19, 23. TDF and TDF/FTC
 12 are Gilead drugs; EFV is a BMS drug.

13 Viread, Truvada, and Atripla were all protected by patents. For example, Truvada was
 14 protected by TDF patents that would expire in 2018 and FTC patents that would expire as late as
 15 2021. Atripla was protected by TDF patents that would expire in 2017, FTC patents that would
 16 expire as late as 2021, and EFV patents that would expire in 2018. *See* Defs.’ Appx. at 4.

17 In 2008, Teva was the first drug manufacturer to file an ANDA for generic Truvada, as
 18 well as the first drug manufacturer to file an ANDA for generic Atripla.²⁷ In 2009, Teva was the
 19 first drug manufacturer to file an ANDA for generic Viread. In each ANDA (either as originally
 20 filed and/or as amended), Teva included a Paragraph IV certification – *i.e.*, stating that certain
 21 patents protecting the brand drugs were either invalid or not infringed. Gilead responded by filing
 22 patent infringement lawsuits so as to protect its TDF patents and FTC patents. *See* McGuire Rpt.

23

24 ²⁶ *See* McGuire Rpt. at 26 n.113 (“Teva retained its statutory 180-day exclusivity with respect to
 25 Viread [TDF], and I have not been asked [by Plaintiffs] to render an opinion as to whether the
 acceleration clauses in the Viread [TDF] agreement are anticompetitive in that context.”).

26 ²⁷ “The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug
 27 Application [instead of a New Drug Application] specifying that the generic has the ‘same active
 ingredients as,’ and is ‘biologically equivalent’ to, the already-approved brand-name drug.” *FTC*
 28 *v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). Essentially, a generic manufacturer is allowed “to
 piggyback on the [brand drug] pioneer’s approval efforts, [thus] ‘speed[ing] the introduction of
 low-cost generic drugs to market’ [and] furthering drug competition.” *Id.*

¶¶ 27-34. For ease of reference, the lawsuits are referred to as the TDF patent infringement suit and the FTC patent infringement suit.

Because Teva was the first ANDA filer with respect to the brand drugs above and had included Paragraph IV certifications in its ANDAs, Teva had the possibility of getting what is known as statutory exclusivity pursuant to the Hatch-Waxman Act.

Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route [in which the generic manufacturer certifies that the relevant patent for the brand drug is invalid or not infringed]. *That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug). During that period of exclusivity no other generic can compete with the brand-name drug. If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly "worth several hundred million dollars."*^[28] Indeed, the Generic Pharmaceutical Association said in 2006 that the “vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.”²⁹ The 180-day exclusivity period, however, can belong only to the first generic to file. Should that first-to-file generic forfeit the exclusivity right in one of the ways specified by statute, no other generic can obtain it.^[29]

Actavis, 570 U.S. at 143-44 (emphasis added).

In April 2013, Gilead and Teva settled the TDF patent infringement suit. *See* Bock Decl., Ex. 16 (TDF Patent Settlement Agreement). The TDF Patent Settlement Agreement included what Plaintiffs call a MFE/MFEP clause and what Defendants call an acceleration clause. In essence, the settlement agreement provided that the default date for Teva’s entry into the market (for generic TDF) would be December 15, 2017; however, if Gilead were to license another company to sell generic TDF, then Teva’s date of entry would be advanced to six weeks earlier than the other company’s entry date. *See* Huttinger Decl., Ex. 16 (TDF Sett. Agmt. § 1.1)

²⁸ That being said, “[t]he [180-day exclusivity] period does not . . . prevent the brand-patentee from marketing its own ‘authorized generic.’” *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 396 (3d Cir. 2015).

²⁹ One example of forfeiture is if a first filer “fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.” *Mylan Labs., Ltd. v. United States FDA*, 910 F. Supp. 2d 299, 302 (D.D.C. 2012).

1 (defining “License Effective Date”). In other words, Teva would be granted a period of
 2 exclusivity during which it would not have to compete with another generic manufacturer. The
 3 MFE/MFEP clause was an important part of the consideration for Teva when it agreed to settle the
 4 TDF patent infringement suit. *See* Huttinger Decl., Ex. 52 (emails, dated 2/17/2013, from
 5 Hashmall to Egosi) (“[Gilead’s negotiator] keeps saying that he wants to reach agreement on time
 6 first, but assumes will work out the other issues. Think I need to make clear that our proposal
 7 necessarily requires exclusivity.”; “The good news is that he more or less confirmed that Gilead is
 8 agreeable to exclusivity.”).

9 Several months after the TDF Patent Settlement Agreement, a bench trial was held in the
 10 FTC patent infringement suit. Evidence was presented from October 8 to 13, 2013. *See* McGuire
 11 Rpt. ¶ 40. Closing arguments were set for mid-February 2014. *See* Huttinger Decl., Ex. 59
 12 (email, dated 1/15/2014, from Rabinovic to Hashmall) (noting that “[w]e have closing on Feb
 13 14”). What took place during the period of October 2013 to February 2014 is critical to the
 14 pending motion.

15 In November 2013, shortly after the bench trial but before closing arguments, Gilead
 16 obtained additional patent protection for Truvada and Atripla – specifically, the first of several
 17 formulation patents that would not expire until (at the earliest) 2024.³⁰ *See* Mot. at 3; Defs.’ Appx.
 18 at 4 & n.4 (indicating that the first formulation patent was obtained in November 2013). (The
 19 formulation patents are also called combination patents.)

20 In mid-January 2014, before closing arguments in the FTC patent infringement suit were
 21 scheduled to begin, Gilead reached out to Teva with a settlement proposal: the settlement would
 22 provide Teva for an entry date of March 2021 (though this was negotiable) and that would likely
 23 cover the new formulation patents (even though they were not part of the litigation). *See*
 24 Huttinger Decl., Ex. 59 (email, dated 1/15/2014, from Hashmall) (stating that Gilead counsel had
 25 offered a settlement proposal). Internally, Teva expressed an interest in the proposal but noted,

27 ³⁰ “[A] formulation patent is a patent that seeks to cover the pharmaceutical formulation of an
 28 active pharmaceutical ingredient, i.e., the unique combination of the active pharmaceutical
 ingredient with excipients that make up the dosage form that is administered to the patient.”
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3857063/> (last visited 1/4/2023).

1 *inter alia*, that it would “like to test the entry date to see if we can get it to late 2019” and that it
 2 would “*need all the usual triggers.*” Huttinger Decl., Ex. 59 (email, dated 1/24/2014, from
 3 Rabinovic to Hashmall) (emphasis added). This was communicated to Gilead. On February 6,
 4 2014, Gilead responded that it was willing to agree to an entry date of January 2021 and that it
 5 would “discuss specifics of usual triggers once we have agreement on [the] above but *assumes*
 6 *same or similar to tenofovir [TDF] deal.*” Huttinger Decl., Ex. 59 (email, dated 2/6/2014, from
 7 Hashmall to Rabinovic) (emphasis added). As noted above, one of the important parts of the TDF
 8 Patent Settlement Agreement was the MFE/MFEP.

9 Less than a week later, Gilead and Teva appeared to be close to reaching a resolution. *See*
 10 Huttinger Decl., Ex. 60 (email, dated 2/12/2014, from Cannella) (“I received a voicemail message
 11 from Hashmall [Teva attorney] last night. He said the reason for the ‘slight delay’ in getting back
 12 to me was because they were ‘moving up the chain of command to get final authority’ on
 13 something ‘I am pretty sure will be a basis to resolve this.’”). On February 13, 2014, Gilead
 14 indicated as follows in a communication with Teva:

- 15 6. We’ll use the ramp-up, acceleration, and other ancillary
 16 provisions of the TDF agreement as the template for drafting
 17 this agreement with the following caveat.
- 18 7. Teva’s entry date for Truvada and Atripla will always be the
 19 earlier of
 20 a. 9/30/20 or
 21 b. *a date that is 180 days earlier than the date Gilead
 22 allows another generic or AG to come on the market.*

23 Huttinger Decl., Ex. 50 (email, dated 2/13/2014, from Cannella to Hashmall) (emphasis added). A
 24 MFE/MFEP clause along those lines was subsequently included in the draft settlement agreement.

25 The FTC Patent Settlement Agreement was formally entered into in April 2014. *See* Bock
 26 Decl., Ex. 17 (FTC Patent Settlement Agreement). Under the settlement agreement, the parties
 27 agreed that Teva could enter the market with generic Truvada and generic Atripla in September
 28 2020 – *i.e.*, about a year before the FTC patents would expire in 2021. However, the settlement
 29 agreement provided that, in certain circumstances, that entry date would be accelerated. Below is
 30 the relevant provision from the FTC Patent Settlement Agreement:

31 “License Effective Date” means, with respect to a particular Teva

1 ANDA Product or a particular FTC Generic Equivalent, on an FTC
2 Combination Product-by-FTC Combination Product basis, the
3 earliest to occur of the following dates:

4 (i) September 30, 2020;

5 (ii) the date on which a Final Court decision is entered holding
6 that each of the ten-asserted unexpired patent claims
7 included in the Licensed FTC Patents that were asserted
8 against Teva in the Litigation is invalid or unenforceable;

9 (iii) the date on which all of the Licensed FTC Patents listed in
10 the Orange Book, with respect to the applicable Gilead
11 Product or FTC Product, has been permanently abandoned or
12 delisted from the Orange Book (excluding any such Licensed
13 FTC Patents as have, as of such date, been held to be invalid
14 or unenforceable);

15 (iv) with respect to Teva ANDA Product only, and except with
16 respect to any Access Use, to the extent that Gilead, any of
17 its Affiliates, or a Third Party (under authorization from
18 Gilead or its Affiliates, by license, sublicense, waiver,
19 covenant not to sue or otherwise) plans or is authorized to
sell the relevant FTC Generic Equivalent in the Territory on
a date that falls any time before September 10, 2021, the date
that is six (6) months prior to (1) the sale thereof by Gilead
or its Affiliate or (2) the earliest permitted sale thereof by
such Third Party, in the Territory; and

20 (v) With respect to Teva ANDA Product only, and except with
21 respect to any Access Use, to the extent that Gilead, any of
22 its Affiliates, or a Third Party (under authorization from
23 Gilead or its Affiliates, by license, sublicense, waiver,
24 covenant not to sue or otherwise) plans or is authorized to
sell the relevant FTC Authorized Generic in the Territory on
a date that falls at any time before September 10, 2021, the
date such FTC Authorized Generic is first sold in the
Territory.

25 Bock Decl., Ex. 17 (FTC Sett. Agmt. § 1.1).

26 Item (i) above is the default date for Teva's entry into the market: September 2020. Items
27 (ii) and (v) above are what Plaintiffs have called MFE ("most favored entry") clauses: Teva's
28 entry date is accelerated so that it is the *same* as the entry date for another generic manufacturer.
For instance, under (ii), if another generic manufacturer proves Gilead's patents invalid or
unenforceable in litigation, then Teva can enter the market on the day of the final court decision
finding the patents invalid or unenforceable. Under (v), if Gilead authorizes the sale of a generic
drug pursuant to its NDA, then Teva can enter the market on the day of the first sale of the
authorized generic.

1 Finally, item (iv) above is what Plaintiffs have called a MFEP (“most favored entry plus”)
 2 clause: Teva’s entry date is accelerated so that it is six months (180 days) *ahead* of the entry date
 3 for another generic manufacturer. In other words, if Gilead were to give a license to another
 4 generic manufacturer to make generic Truvada or Atripla, then Teva’s date of entry would be six
 5 months (180 days) ahead of any sale by the other generic manufacturer.

6 Plaintiffs argue that, but for the MFE/MFEP clauses in the FTC Patent Settlement
 7 Agreement, the parties would have negotiated an earlier entry date for Teva purposes of settlement
 8 (*i.e.*, before September 2020), *or* Teva would have waited to get a decision in the patent
 9 infringement litigation – both situations being informed by the fact that “Teva was very likely to
 10 get a finding that the patents were invalid.” Opp’n at 2; *see also* Opp’n at 5 (arguing that, if
 11 Gilead and Teva had settled without a MFE/MFEP, then “rational manufacturers would have
 12 agreed on an entry date of May 2019”; if Teva had won the lawsuit, then generic entry for Truvada
 13 and Atripla would have taken place in February 2018 (once the *TDF* patents had expired)³¹). But,
 14 Plaintiffs contend, the MFE/MFEP clauses gave Teva more benefits, particularly compared to the
 15 litigation route. Although Teva was likely to prevail in the patent infringement suit, Teva had
 16 *forfeited* the 180 days of statutory exclusivity to which it was entitled as the first ANDA filer for
 17 Truvada and Atripla; therefore, a “victory on invalidity would also allow other generic[]
 18 [manufacturers] to enter the market when [Teva] did. Teva would make orders of magnitude more
 19 money if other generic[] [manufacturers] were not there to compete.” Opp’n at 2. According to
 20 Plaintiffs, the MFE/MFEP clauses gave *contractual* exclusivity to Teva for 180 days (effectively
 21 restoring at least in part the forfeited 180-day *statutory* exclusivity³²); Teva explicitly
 22 acknowledged that it was getting the benefit of contractual exclusivity with the settlement. *See*

23
 24
 25 ³¹ Both Truvada and Atripla have TDF as a component (in addition to FTC).

26 ³² Defendants’ expert Mr. Hoxie explains why it would not be possible for parties to *restore*
 27 statutory exclusivity as a contractual matter. *See* Bock Decl., Ex. 7 (Hoxie Rpt. ¶ 86) (“Once Teva
 28 forfeited its 180-day Hatch-Waxman exclusivity, there was no way to ‘restore’ that advantage;
 there was no way to prevent other ANDA filers from obtaining FDA final approval and launching
 their products, assuming these ANDA filers had confidence they would ultimately prevail in the
 patent litigation.”).

1 Huttinger Decl., Ex. 25 (Hashmall Depo. at 30-31, 69-70, 85, 91).³³ Teva never paid Gilead a
 2 royalty for this contractual exclusivity even though Gilead presumably would have charged for
 3 this benefit as part of an arms-length transaction unrelated to a settlement agreement. Thus,
 4 Plaintiffs contend that the settlement with the MFE/MFEP provisions was one of “pay for delay”
 5 (*i.e.*, a reverse payment settlement agreement as described by the Supreme Court in *Actavis*). *See*
 6 Opp’n at 3. In short, Gilead effectively paid Teva to delay its entry. *See* McGuire Rpt. ¶ 117
 7 (“An acceleration clause costs the brand [A] brand may not fully collect the royalties or other
 8 payments it would otherwise collect if the conditional license represented by an acceleration
 9 clause were part of an arms-length transaction unrelated to a patent settlement. Forgoing royalties
 10 on a licensing deal constitutes a profit sacrifice”).

11 Defendants disagree that there was any exclusivity under the settlement agreement,
 12 pointing out, *e.g.*, that, with the MFEP clause, Teva’s entry date is accelerated only where another
 13 generic manufacturer is *licensed* to make a generic version of the brand drug; there is no
 14 acceleration where a generic manufacturer launches its generic drug “*at risk*” (*i.e.*, without a
 15 license from Gilead).

16 Plaintiffs counter that at-risk launch was never a serious concern, as demonstrated by the
 17 fact that “every other generic [manufacturer] delayed its entry until exactly Day 181 after Teva’s
 18 entry.”³⁴ Opp’n at 3; *see also* Opp’n at 11 (citing to Dr. McGuire’s report in support of the
 19 position that an at-risk launch was very unlikely). Plaintiffs also assert that the MFE/MFEP

21 ³³ Mr. Hashmall was Teva’s outside counsel and negotiator. In his deposition, he testified, *inter*
 22 *alia*, that:

- 23 • The provision where Teva would get 180 days earlier than the date Gilead would
 allow any other generic manufacturer was a form of contractual exclusivity. *See*
 Huttinger Decl., Ex. 25 (Hashmall Depo. at 69-70, 85, 91).
- 24 • “[E]xclusivity would provide value to the client” because, “if Teva were the only
 generic [manufacturer] on the market for a period of time, that would provide
 monetary value to Teva.” Huttinger Decl., Ex. 25 (Hashmall Depo. at 30-31).

25
 26 ³⁴ As noted in Defendants’ opening brief, at the time that Gilead and Teva entered into the FTC
 Settlement Agreement in April 2014, “three other generic manufacturers – Cipla, Lupin, and
 Mylan – had filed Paragraph IV ANDAs for Truvada, Atripla, or both. After the Teva FTC
 Settlement, Gilead settled with a total of ten other generic manufacturers as to Truvada and
 Atripla.” Mot. at 7.

1 clauses served to delay the entry of other generic manufacturers until Day 181 because the clauses

2 substantially degrad[ed] both avenues for them to try to enter
3 sooner: litigation and settlement. First, “the MFE degrades the
4 subsequent generic[] [manufacturer’s] expected value of profits *from*
5 *[litigating]*.” Ex. 3, McGuire MFE/P Rpt. ¶ 128. Second, the
6 MFE/P severely degrades their likelihood of getting an earlier entry
7 date than Teva *through settlement*: those “earlier entry dates . . . are
8 no longer profitable to Gilead because of the severe profit loss from
9 accelerating Teva’s entry date.” *Id.* “The net effect of the MFE and
10 MFE+ clauses is to push the bargaining range later in time, moving
11 the likely settlement date between Gilead and the subsequent
12 generic[] [manufacturers] from the Teva date . . . to six months
13 later.” *Id.*

14 Opp’n at 4 (emphasis in original). Thus, there is a plausible claim that, by virtue of the
15 MFE/MFEP, Teva was afforded, in practical effect, exclusivity which impacted competition. The
16 question is whether Plaintiffs have created a genuine dispute of fact with respect to their
17 MFE/MFEP claims.

18 **B. Antitrust Injury**

19 Antitrust claims generally require a plaintiff to prove (1) anticompetitive conduct and (2)
20 antitrust injury. *See, e.g., ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012)
21 (noting that “[s]ections 1 and 2 of the Sherman Act . . . each include an anticompetitive conduct
22 element, although each statute articulates that element in a slightly different way”; furthermore,
23 “to establish an actionable antitrust violation,” a plaintiff must prove not only that the defendant
24 engaged in anticompetitive conduct, but also that the plaintiff suffered antitrust injury). According
25 to Defendants, there is no genuine dispute that, with respect to the FTC Patent Settlement
26 Agreement, Plaintiffs cannot prove either element. Because Defendants address antitrust injury
27 before anticompetitive conduct, the Court does the same.

28 The antitrust injury claimed by Plaintiffs is delayed entry into the market by a generic
29 manufacturer – either Teva or another generic manufacturer. Defendants argue that there is a
30 causation problem, specifically, that there is no evidence that (1) Teva agreed to a delayed entry as
31 a result of the MFE/MFEP clause settlement agreement or that (2) another generic manufacturer(s)
32 delayed entry into the market as a result of the clause.

1 1. Delay by Teva

2 Under the FTC Patent Settlement Agreement, the default entry date for Teva to sell generic
 3 Truvada and Atripla was September 2020.³⁵ Plaintiffs' theory is that, but for the MFE/MFEP
 4 clause in the settlement agreement, Teva would have secured an entry date *earlier* than September
 5 2020 because it was likely to prevail in the FTC patent infringement suit. According to Plaintiffs,
 6 if Teva and Gilead had settled the litigation without any MFE/MFEP, then they would have
 7 negotiated an agreement that would have allowed Teva to enter the market in May 2019;
 8 alternatively, if Teva had continued to litigate, then, upon prevailing in the lawsuit, it would have
 9 been able to enter the market in February 2018 (once the TDF patents expired).

10 a. Teva's Subjective Assessment

11 According to Defendants, Plaintiffs' theory is flawed because Teva did not think that it
 12 was likely to prevail in the FTC patent infringement litigation – or with a challenge to Gilead's
 13 new formulation patents which were not a part of the litigation and would not expire until (at the
 14 earliest) 2024. Defendants maintain that, before any MFE/MFEP clause was expressly
 15 contemplated, Teva thought the best it could do (*i.e.*, based on the merits of the patents alone) was
 16 to get an entry date of November 2020. This date was *worse* than the September 2020 default
 17 entry date that Teva ended up getting under the FTC Patent Settlement Agreement. Thus,
 18 Defendants assert that Teva could not have delayed entry into the market as a result of the
 19 MFE/MFEP. *See* Mot. at 11 (arguing that "Teva was willing to accept" the entry date of
 20 September 2020 because "it saw only a 17.5% chance of doing better than November 2020 if it
 21 continued to litigate, and an 82.5% chance of doing worse").

22 As an initial matter, Plaintiffs criticize Defendants' argument because it focuses solely on
 23 Teva. In other words, Plaintiffs argue that Defendants are incorrect in asserting that the question
 24 is what Teva would have done in the but-for world (*i.e.*, without the MFE/MFEP); rather, the
 25 question is what Teva *and Gilead* would have done (*i.e.*, what would their negotiation have been

27 ³⁵ This date of entry was before the relevant patents protecting Truvada and Atripla would expire
 28 on their face. The FTC patents would expire at the latest in September 2021, and the formulation
 29 patents that Gilead acquired after initiating the patent infringement suits were not due to expire
 30 until 2024.

1 without the MFE/MFEP); Defendants have considered only half of the equation. *See* Opp'n at 12.
 2 Plaintiffs add that, because only Teva has waived attorney-client privilege, Defendants have not
 3 provided any information about Gilead's contemporaneous, subjective assessment of the patent
 4 infringement litigation or the strength of the formulation patents. *See* Opp'n at 20. Plaintiffs
 5 make a fair legal point – *i.e.*, both Teva and Gilead's beliefs matter in assessing what a
 6 hypothetical negotiation would have yielded. *Cf. Asetek Danmark A/S v. CMI USA Inc.*, 852 F.3d
 7 1352, 1362 (Fed. Cir. 2017) (noting that, in a patent infringement case, a prevailing patent owner
 8 "may receive a reasonable royalty" and a reasonable royalty is calculated "using the common
 9 hypothetical negotiation approach . . . under which the finder of fact 'attempts to ascertain the
 10 royalty upon which the parties would have agreed had they successfully negotiated an agreement
 11 just before infringement began'").

12 Moreover, even if the Court were to focus on Teva's side of the negotiation equation,
 13 Defendants' position that "Teva's contemporaneous subjective views" regarding its likelihood of
 14 success are "dispositive" lacks merit.³⁶ Mot. at 11-12. Relying exclusively on Teva's records of
 15 its subjective views without any critical inquiry would be improper. This would bar the trier of
 16 fact from assessing Teva's credibility. And as Plaintiffs point out, there is an inherent danger in
 17 automatically crediting Teva's views: an "antitrust violation taints [a defendant's] 'real world'
 18 conduct. In addition to eliminating the generic [manufacturer's] incentive to negotiate for the
 19 earliest possible entry date, the violation also incentivizes the generic [manufacturer] to 'change
 20 sides' . . . and assert that the patents were strong rather than weak." Opp'n at 13. There is a risk
 21

22 ³⁶ Contrary to what Defendants suggest, the Supreme Court did not hold in *Actavis* that subjective
 23 beliefs are dispositive. Admittedly, the Supreme Court did state as follows:
 24

25 Although the parties may have reasons to prefer settlements that
 26 include reverse payments, the relevant antitrust question is: What
 27 are those reasons? If the basic reason is a desire to maintain and to
 28 share patent-generated monopoly profits, then, in the absence of
 some other justification, the antitrust laws are likely to forbid the
 arrangement.

29 *Actavis*, 570 U.S. at 158. But as Plaintiffs point out, the Supreme Court was only considering the
 30 issue of whether there was anticompetitive conduct, and not, as in the case at bar, the issue of
 31 whether there was antitrust injury. Defendants have not demonstrated why the two contexts
 32 should be equated.

1 of unilateral manipulation of the official record of the participants' intent in a way that would
2 validate their conduct.

3 More fundamentally, the inquiry should focus on what a rational generic manufacturer
4 would have done if it were in Teva's position. *See Opp'n at 12.* This was essentially the approach
5 of the district court *In re Zetia (Ezetimibe) Antitrust Litigation*, No. MDL No. 2:18-md-2836, 2022
6 U.S. Dist. LEXIS 172065 (E.D. Va. Aug. 15, 2022):

7 Without the alleged anti-competitive conduct, a jury may conclude
8 that Glenmark's actions would be those of a Reasonable Firm, and
9 Jon Clark's opinion is helpful to the trier of fact in evaluating
causation.

10 The relevant question is how a reasonable profit-maximizing
11 company would behave without the alleged anti-competitive
12 conduct. *See Pls.' Opp'n* (ECF No. 1142, at 22 & n.88) (citing
13 cases). Antitrust cases "presume the existence of rational economic
14 behavior in the hypothetical free market." *Dolphin Tours, Inc. v.*
15 *Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985)
16 (citing *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th
17 Cir. 1981)); *see also Lidoderm*, 296 F. Supp. 3d at 1162 (describing
18 "the antitrust context, where but-for worlds are considered and
19 profit-maximizing goals assumed"); *id.* at 1179 n.42 (reciting "a
20 presumption of economical rationality").

21 *Id.* at *56-57. The *Zetia* court relied on the Ninth Circuit's decision in *Dolphin Tours, Inc. v.*
22 *Pacifico Creative Service, Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985). There, the appellate court
23 noted that the antitrust plaintiff had

24 attempted to establish its lost profits by projecting the market share
25 that it would have attained absent the anticompetitive activity. In
26 using this approach, [the plaintiff] must presume the existence of
27 rational economic behavior in the hypothetical free market. This
28 includes a rational price differential between [the plaintiff's] prices
and defendants' prices based on all competitors attempts to
maximize their own profits, and the potential entry of other
competitors into the market.

29 *Id.* at 1511. Other cases are in accord. *See In re Solodyn (Minocycline Hydrochloride) Antitrust*
30 *Litig.*, No. CV 14-MD-02503, 2018 WL 734655, at *2 (D. Mass. Feb. 6, 2018) (stating that the
31 expert "Tupman cannot opine about what [the generic manufacturer] Impax thought, [but]
32 Tupman may still opine about how a reasonable company sitting in Medicis' shoes may analyze
33 the business context"); *King Drug Co. of Florence v. Cephalon, Inc.*, No. 2:06-cv-1797, 2015 U.S.

1 Dist. LEXIS 135264, at *39 (E.D. Pa. Oct. 5, 2015) (stating that “[t]he challenged experts’
2 analyses are largely derived from the economic information available to Defendants at the time of
3 the settlement agreements, and these experts opine on what a rational, objective actor would have
4 considered in light of that information[;] [w]hile Plaintiffs assert that this type of objective
5 analysis is not relevant to the issues a jury would need to consider in conducting an *Actavis*
6 inquiry, they provide no support for this assertion,” and “[o]ther courts have permitted this type of
7 objective economic analysis in reverse-payment settlement cases”).

8 Furthermore, even on Defendants’ terms, Teva’s contemporaneous subjective views were
9 not as clear cut as Defendants have suggested. Below is a brief timeline of what Teva’s beliefs
10 were during the critical period of October 2013 to November 2014.

- 11 • **Pre-October 2013.** In the months before the FTC patent infringement trial, Teva’s
12 outlook on the case was not positive. For example, in a January 2013 email, Teva’s
13 Chief IP Counsel, Ms. Julie, noted that Teva had a “reasonable shot of success” in
14 the *TDF* patent infringement suit but indicated that that was not the case for the
15 *FTC* patent infringement suit. Bock Decl., Ex. 57 (email). In a July 2013 email,
16 Ms. Julie stated that the *FTC* patents were “troubling” and “our chances . . . are
17 low.” Bock Decl., Ex. 46 (email). And in another email from July 2013, Ms.
18 Rabinovic, Teva’s in-house IP counsel supervising the case, stated that “I am tired
19 of looking through my email to figure out how many times I told them the [FTC]
20 patents were difficult to overcome.” Bock Decl., Ex. 47 (email).
- 21 • **October 3, 2013.** However, shortly before the bench trial began in the *FTC* patent
22 infringement case, Teva seemed to have a more positive outlook on its chances in
23 the trial. Ms. Rabinovic noted in an email that Gilead had made a settlement
24 proposal and stated that “[w]e are feeling somewhat more positive about our
25 defenses”; “[w]e think we should make an aggressive offer for an entry date
26 between the 2016 and 2021 dates, around the December 2017 date we already
27 agreed on for a Viread launch” because “the case isn’t so bad now that the case is
28 narrow.” Huttinger Decl., Ex. 66 (email).

- 1 • **October 8-13, 2013.** Evidence was presented in the FTC patent infringement
2 bench trial. Closing arguments were set for February 2014.
- 3 • **November 2013.** Following the presentation of evidence at the bench trial, Ms.
4 Julie asked her team to prepare assessments for the patents involved in the FTC
5 patent infringement suit, as well as the new formulation patents. (According to Ms.
6 Julie, the assessment was not for purposes of the infringement suit; rather, it was
7 “in connection with Teva’s project to develop certain HIV products[,] internally
8 designated new therapeutic entities (NTEs).” Bock Decl., Ex. 65 (Julie Decl. ¶ 8).)
9 The team (consisting of a patent attorney and a patent agent) concluded that, based
10 on the FTC patents and the new formulation patents, “the odds that Teva would be
11 able to start selling in the United States before 2021 were 30%.” Bock Decl., Ex.
12 65 (Julie Decl. ¶ 8). Although these were low odds, the team also concluded that,
13 once the FTC patents expired in 2021, “the odds that Teva could start selling [were]
14 75%” – *i.e.*, in spite of the new formulation patents. Bock Decl., Ex. 65 (Julie
15 Decl. ¶ 9). The team “set the odds of overcoming the [formulation] patents at 75%
16 in light of the fact that comparable European patents owned by Gilead had been
17 revoked in the first instance in opposition proceedings before the European Patent
18 Office (EPO) in 2011, and we hoped that similar arguments might succeed in
19 District Court litigation in the United States.” Bock Decl., Ex. 65 (Julie Decl. ¶ 9);
20 *see also* Huttinger Decl., Ex. 67 (ECF Page 746) (email, dated 11/13/2013) (in a
21 legal slide, indicating that a certain product containing TDF/FTC had a 75%
22 probability of launching in the United States in 2021). In mid-November 2013, one
23 document reflected an even higher probability of launching in 2021 – 85%. *See*
24 Huttinger Decl., Ex. 72 (ECF Page 797) (email, dated 2/10/2014, from Rabinovic
25 to Julie) (attaching document dated 11/11/2013).
- 26 • **January 2014.** A slide presentation continued to refer to a 75% probability of
27 launching in the United States in 2021 – *i.e.*, in spite of the new formulation patents
28 which would not expire until 2024. *See* Huttinger Decl., Ex. 69 (slide).

- 1 • **Early to mid-January 2014.** An invalidity opinion on one of the new formulation
2 patents (the ‘397), which had been prepared by Teva’s outside counsel, was
3 circulated. *See* Huttinger Decl., Ex. 71 (email circulating opinion letter, dated
4 11/27/2013). In the opinion letter, counsel stated its belief that certain claims of the
5 ‘397 patent were invalid and that Teva would not infringe with respect to the valid
6 claims. *See* Huttinger Decl., Ex. 71 (letter). Somewhat confusingly, Ms. Julie
7 testifies in a declaration that, after getting the opinion letter and discussing the
8 matter with her colleagues, she “concluded that Teva’s potential invalidity defense
9 with respect to the [new formulation] patents had a substantially lower probability
10 of success in U.S. District Court under U.S. patent law than the probability of
11 ultimate success on the European patents at the EPO under European patent law,”
12 and so she “revise[d] the odds of success for the [formulation] patents down to 30-
13 40%.” Bock Decl., Ex. 65 (Julie Decl. ¶ 10); *see also* Huttinger Decl., Ex. 68
14 (email, dated 1/14/2014, from Rabinovic to Julie) (suggesting revision down to
15 30% probability of launching in the United States in 2021, *i.e.*, rather than 75%).
- 16 • **Mid-January 2014.** At about this same period, Gilead contacted Teva and offered
17 a settlement proposal for the FTC patent infringement suit. Under the proposal,
18 Teva would get an entry date of March 2021 (though this appeared negotiable) and
19 Gilead would likely agree that the settlement would cover not just the FTC patents
20 but also the new formulation patents. *See* Huttinger Decl., Ex. 43 (email, dated
21 1/15/2014, from Hashmall).
- 22 • **February 10, 2014.** Ms. Julie commented in an email to her supervisor, Richard
23 Egosi (Teva’s Chief Legal Officer), that Teva and Gilead “have had a bunch of
24 back and forth” and, “[a]fter much negotiation, we just received an offer from them
25 . . . which would put our entry date in November 2020. Gilead is willing to give us
26 a license to the 2024 [formulation] patents as of the entry date as part of the
27 settlement.” Huttinger Decl., Ex. 74 (email, dated 2/10/2014, from Julie to Egosi).
28 Ms. Julie stated that “it makes sense to try to get the best settlement we can now,”

particularly because, “[i]f Gilead were to enforce [the formulation] patents (which they have indicated they will if we don’t settle), we believe our odds on prevailing are 30-40%.”¹¹ Huttinger Decl., Ex. 74. Ms. Julie added that, with respect to the FTC patents (which were due to expire in 2021), “[w]e felt like trial went well for us, but it is difficult to give odds of greater than 50% (certainly before closing arguments).”¹² Huttinger Decl., Ex. 74; *see also* Bock Decl., Ex. 65 (Julie Decl. ¶¶ 3-4, 7) (discussing this email). Mr. Egosi approved moving forward. *See* Bock Decl., Ex. 42 (email, dated 2/11/2014).

- **February 12, 2014.** Ildiko Mehes, Teva’s Vice President and General Counsel for North America, subsequently passed on Ms. Julie’s assessment to Allan Oberman, Teva Americas President and CEO. *See* Bock Decl., Ex. 49 (email, dated 2/12/204, from Mehes to Oberman). Fred Killion, Teva’s Deputy Chief Legal Officer, then sent an email to Ms. Mehes and Mr. Oberman providing odds on what would happen if Teva did not settle: “If we DON’T SETTLE,” there was (1) “[a] 17.5 percent chance of being able to enter 2+ years EARLIER than the settlement date (50% chance of winning this case x 35% chance of successfully challenging the 2 new [formulation] patents that expire in 2024),” and (2) “[a]n 82.5 percent chance of being unable to enter until LATER than the settlement date.” Bock Decl., Ex. 49.

It appears Teva's views on its likelihood of success varied over time – for both the FTC patents that were the subject of the patent infringement trial and the new formulation patents. By February 2014, when Gilead and Teva had basically reached a settlement, Teva seemed to believe it had a decent shot of success with respect to the FTC patents (50%). This seemed a more positive outlook compared to the pre-October 2013 period. While, in February 2014, Teva did claim a low chance of success on the formulation patents (30-40%), a few months earlier it had viewed its probability of success much more favorably (75% or more), and it is not entirely clear from the record *why* Teva's views on the likelihood of had changed. As indicated above, the opinion letter on one of the new formulation patents actually seemed positive with respect to

1 Teva's prospects, and Ms. Julie does not explain in her declaration submitted as part of the
 2 summary judgment briefing why there was a lower probability of succeeding in the United States
 3 compared to Europe.

4 In their papers, Plaintiffs argue that, in the absence of a real explanation, one could infer
 5 that Teva's change in views was related to its settlement discussions going on with Gilead:

6 [A] jury may reasonably conclude that Ms. Julie's revised February
 7 10 purported reassessment was prompted by *Gilead's February 6*
confirmation that it would agree to an MFE/P the "same or similar
 8 *to tenofovir [TDF] deal."*³⁷ She knew that a six-week MFE/P (a la
 9 TDF) would generate more than \$350 million profits for Truvada
 10 and Atripla. Within hours of learning that a deal would include an
 11 MFE/P, she for the first time solicited [Teva's] NTE [new
 12 therapeutic entity] team's views on a potential settlement. She
 13 learned that they would support settlement only if the odds on the
 14 [formulation] patents were low.³⁸ The jury may conclude that she
 15 simply gave the NTE team the low odds they required, securing
 16 their support for the MFE/P-laden settlement.

17 Opp'n at 20 (emphasis in original and added).³⁹

18 Defendants criticize Plaintiffs for not deposing Ms. Julie or other Teva executives to drill
 19 down why Teva's views changed. *See Reply at 8.* Although it does seem odd that Ms. Julie or
 20 other Teva executives were not deposed, an inference can still be made in Plaintiffs' favor (as
 21 should be done at summary judgment) because Ms. Julie did not sufficiently explain her change in
 22 views, not even in the declaration she submitted as part of the summary judgment briefing.

23 In their reply brief, Defendants protest that

24 it does not matter whether Ms. Julie personally believed the

25 ³⁷ *See* Huttinger Decl., Ex. 60 (email, dated 2/6/2014, from Hashmall to Rabinovic) (addressing
 26 settlement discussions; taking note of Gilead's comment that "[w]ill discuss specifics of usual
 27 triggers once we have agreement on above but assumes same or similar to tenofovir [TDF] deal").
 28 For the TDF Settlement Agreement, there was an acceleration clause with a six-week exclusivity
 29 period.

30 ³⁸ *See* Huttinger Decl., Ex. 76 (email exchange, dated 2/6/2014, between Julie and Kogan) (Ms.
 31 Julie asking, "Are you ok with [the settlement]?" and Ms. Kogan responding that "the decision
 32 depends on the [formulation] patent strength[;] [i]f we can easily invalidate them, I wouldn't settle
 33 (from a pure NTE point of view) [but] [i]f the [formulation] patents are a barrier, then I would
 34 settle").

35 ³⁹ This underscores the point discussed *supra*: there is a risk of manipulation of the record by
 36 participants to justify or validate their conduct.

assessment of patent strength she expressed to senior management, or whether, as Plaintiffs baselessly suggest, she instead had some secret motive to express pessimism. It is undisputed that Teva's relevant decision makers – the CLO [Chief Legal Officer] and the President/CEO – approved the FTC Settlement based on the final analysis from counsel that Teva had only a combined 17.5% chance to prevail on the patents[⁴⁰]. . . .

• • • •

Moreover, Plaintiffs' argument is truly bizarre: that a senior attorney in Teva's general counsel's office deceived senior management to gin up support for a settlement. This theory has no factual support and borders on frivolous. It is certainly insufficient to defeat summary judgment: "A party cannot create a dispute of fact by simply questioning the credibility of a witness."

Reply at 10. Although Defendants' argument is not entirely lacking in merit, the issue here is whether there are genuine disputes of fact that would preclude summary judgment. Here Plaintiffs have articulated a basis for questioning Ms. Julie's change in views about Teva's likelihood of success.⁴¹

b. Entry Date Negotiated Before MFE/MFEP

Defendants argue that, even if the Court does not rule in its favor on the above argument, Plaintiffs' theory must still be rejected because the evidence shows that Gilead and Teva never negotiated a MFE/MFEP until *after* they had already reached agreement on the default entry date of September 2020, and thus this was no quid pro quo therefor. *See, e.g.*, Bock Decl., Ex. 65 (Julie Decl. ¶¶ 7, 12) (testifying that, in her email of 2/10/2014 (in which she recommended settlement with Gilead for an entry date some time in the fourth quarter of 2020), she did not mention a provision that would give Teva some kind of exclusivity because, "to the best of my recollection, at that time no such exclusivity provision had been discussed between the parties"); Bock Decl., Ex. 12 (Pletcher Depo. at 70, 81) (General Counsel for Gilead at the time of the FTC Settlement agreement testifying that, "in this negotiation with Teva, there were two parts[:] The first part was what's the date going to be, and after that, you negotiate terms of an agreement");

⁴⁰ 17.5% = 50% chance of winning the FTC patent infringement trial x 35% chance of successfully challenging the formulation patents that would expire in 2024.

⁴¹ There may also be an argument that a “cat’s paw” theory should apply – *i.e.*, that so long as the company decisionmakers were influenced by Ms. Julie, that is a sufficient basis to hold the company liable.

1 also testifying that, until the draft FTC settlement agreement “went out, the only terms that we had
 2 discussed were the date” – *i.e.*, not the 180-day contractual exclusivity provision). Defendants
 3 thus contend there is no evidence that Teva agreed to a delayed entry date *in exchange* for getting
 4 a MFE/MFEP. Defendants admit that “there was likely an assumption that the final settlement
 5 would include *some* form of acceleration provision [because] the vast majority of Hatch-Waxman
 6 Act settlements include such provisions.” Mot. at 15 (emphasis in original). But, because Gilead
 7 and Teva did not “negotiate the *specific terms* of the acceleration provision until after they agreed
 8 to the September 2020 entry date,” Mot. at 15 (emphasis added), no reasonable jury could say the
 9 entry date was impacted by the acceleration clause.

10 The problem with Gilead’s argument is that there is a disputed question of fact – *i.e.*,
 11 whether there was an implicit agreement on an acceleration clause with exclusivity at the time
 12 Gilead and Teva reached agreement on the default entry date of September 2020.

13 As noted above, the parties started settlement discussions in mid-January 2014, prior to
 14 closing arguments. Internally, Teva expressed an interest in Gilead’s settlement proposal but
 15 noted, *inter alia*, that it would “like to test the entry date to see if we can get it to late 2019” and
 16 that it would “*need all the usual triggers*.” Huttinger Decl., Ex. 59 (email, dated 1/24/2014, from
 17 Rabinovic to Hashmall) (emphasis added). On February 6, 2014, Gilead responded that it was
 18 willing to agree to an entry date in January 2021 and that it would “discuss specifics of usual
 19 triggers once we have agreement on [the] above but *assumes same or similar to tenofovir [TDF]*
 20 *deal*.” Huttinger Decl., Ex. 59 (email, dated 2/6/2014, from Hashmall to Rabinovic) (emphasis
 21 added). As noted above, one of the important parts of the TDF Settlement Agreement was the
 22 MFE/MFEP.

23 Furthermore, it is questionable whether Gilead and Teva would *conclusively* agree on an
 24 entry date without knowing what the other terms of the settlement would be. Certainly, a contrary
 25 inference can be drawn. Indeed, Plaintiffs make a fair argument that “[i]t defies reason that the
 26 parties had already ‘definitively’ agreed on an entry date and then Gilead just gave a \$600 million
 27 gift to Teva [*i.e.*, the royalties that Gilead could have charged Teva for giving Teva contractual
 28 exclusivity].” Opp’n at 15. “It also defies the testimony of Teva’s negotiator, Mr. Hashmall, that

1 getting the six month MFE/P was ‘key to [Teva’s] willingness to settle.’” Opp’n at 15. At the
 2 very least, given that reasonable inferences are to be drawn in favor of the non-moving party for
 3 summary judgment purposes, there is a disputed issue of fact here.

4 2. Other Generic Manufacturers

5 Given that Plaintiffs have evidence to support their position that Teva did agree to delay
 6 entry because of the MFE/MFEP, that is enough for them to get by summary judgment. In other
 7 words, the Court need not examine whether other generic manufacturers also delayed their entry
 8 into the market as a result of the MFE/MFEP. However, out of an abundance of caution, the Court
 9 considers this issue and concludes that it also warrants denial of summary judgment: there is a
 10 genuine dispute as to whether the MFE/MFEP delayed the entry of other generic manufacturers.

11 Defendants argue that the MFE/MFEP could not have been a deterrence to other generic
 12 manufacturers because it did *not* accelerate Teva’s entry date if a generic manufacturer decided to
 13 launch its generic drug *at risk* (*i.e.*, without a license from Gilead). According to Defendants,
 14 “because none of the settlements between Gilead and Teva contained an at-risk launch
 15 acceleration clause, generics had increasing incentive to launch at risk as additional generics
 16 settled. Any generic that settled would not be able to launch earlier than the LED [licensed entry
 17 date] if a non-settling generic opted to launch at risk and take its chances in court.” Hoxie Rpt. ¶
 18 85; *see also* Hoxie Rpt. ¶ 106 (“Once Teva had settled and agreed to defer its launch, other
 19 generics would have a golden opportunity and strong incentive to launch – if they felt confident
 20 that they would not ultimately lose the patent litigation. A strong competitor had left the field.
 21 There was no 180-day exclusivity blocking FDA approval. The litigation was well advanced.
 22 Teva’s launch would not be accelerated by an at-risk launch by another generic.”). And
 23 “[c]onsistent with these incentives, . . . most of the later generic filers who filed Paragraph IV
 24 challenges did so only *after* Teva entered into its settlement with Gilead.” Mot. at 16-17
 25 (emphasis in original); *see also* Hoxie Rpt. ¶ 80) Defendants concede that none of the generic
 26 manufacturers actually went on to launch at risk (either the ten who had filed ANDAs for Truvada
 27 or the eight who had filed ANDAs for Atripla), *see* Hoxie Rpt. ¶ 80, but suggest that was only
 28 because of the strength of the patents at issue. *See* Hoxie Rpt. ¶ 102 (“Nothing in the settlement

1 agreement prevented other generic companies from obtaining FDA approval and launching a
 2 product. The obstacle to launch was not the settlement agreement. The obstacle was the Orange
 3 Book-listed patents, which Teva and the other ANDA filers ultimately chose to respect rather than
 4 challenge.”).

5 But there is a genuine dispute of fact here because the strength of the FTC patents – as well
 6 as the formulation patents – is not clear and therefore the fact that no generic manufacturer
 7 launched at risk and instead settled with Gilead for an entry date of “Day 181” (*i.e.*, 180 days after
 8 Teva) gives rise to an inference that they agreed to delay entry because of the MFE/MFEP in the
 9 FTC Patent Settlement Agreement between Gilead and Teva. *See also* Opp’n at 4 (asserting that a
 10 “MFE/P severely degrades [a generic manufacturer’s] likelihood of getting an earlier entry date
 11 than Teva through settlement: those “earlier entry dates . . . are no longer profitable to Gilead
 12 because of the severe profit loss from accelerating Teva’s entry date”). Plaintiffs have also
 13 submitted evidence suggesting that an at-risk launch (that would not trigger acceleration of Teva’s
 14 entry date) was not likely even though that door was technically left open by the settlement
 15 agreement. For example, Plaintiffs’ expert Mr. Clark explains that not many generic
 16 manufacturers have the financial resources to launch at risk (*i.e.*, launching at risk exposes the
 17 generic manufacturer to potential damages – which can be very high for blockbuster drugs). *See*
 18 *Huttinger Decl.*, Ex. 7 (Clark Rpt. ¶ 24). In addition, Plaintiffs’ expert Dr. McGuire notes as
 19 follows:

20 186. . . . Although at-risk entry is not uncommon for first filers,
 21 it is unusual a non-first filer to launch at risk after the first
 22 filer has settled.

23 187. The circumstances here make at-risk entry even less likely.
 24 The *TDF* patents did not expire for many years after Gilead
 25 had initiated [*FTC*] litigation against the earliest ANDA
 26 filers, giving the litigation ample time to reach a legal
 27 conclusion with respect to the patents at issue in the Teva
 28 litigation before entry by subsequent filers was possible.
 Any potential at-risk entrant would have little to gain relative
 to its potential damages. Lastly, I am unaware of evidence
 that Gilead, Teva, or any of the other generics expected that
 a generic would launch at risk after the Gilead-Teva
 Agreement was signed (or any time time). In fact, no
 generics launched at risk.

1 McGuire Rpt. ¶¶ 186-87 (emphasis added); *see also* McGuire Reb. Rpt. ¶¶ 85-87 (going into
 2 further details as to why the generic manufacturers were not likely to launch at risk). Another
 3 expert of Plaintiffs makes fair criticisms of Defendants' analysis – noting, *e.g.*, that the defense
 4 expert, Mr. Hoxie, did not take into account that an at-risk launch would still “require FDA
 5 approval which, if the brand-drug company sues the Paragraph IV applicant within 45 days, could
 6 not occur for at least 30 months.” Clark Reb. Rpt. ¶ 36.

7 3. Summary

8 For the foregoing reasons, the Court rejects Defendants' argument that they are entitled to
 9 summary judgment because there is no evidence that the MFE/MFEP delayed either Teva's entry
 10 date or the entry date of other manufacturers. There is a genuine dispute of fact on those matters.

11 C. Anticompetitive Conduct

12 Defendants argue that, even if there may be a genuine dispute of fact on antitrust injury,
 13 there is no genuine dispute of fact on anticompetitive conduct. Defendants take the position that
 14 Plaintiffs are asserting a reverse payment theory under the Supreme Court's *Actavis* decision, *see*
 15 *Actavis*, 570 U.S. at 148 (noting that, where a plaintiff sues a defendant for patent infringement,
 16 and the defendant does not have any claim that the plaintiff is liable to it for damages, then it is an
 17 “unusual” settlement for the plaintiff to pay the defendant money under the settlement agreement),
 18 but no reverse payment (*i.e.*, profit sacrifice) was ever made by Gilead to Teva (*i.e.*, in exchange
 19 for the delayed entry date of Teva).

20 1. Non-*Actavis* Theory

21 As an initial matter, the Court notes that Plaintiffs are not clearly limiting themselves to a
 22 reverse payment theory under *Actavis*. If Gilead was able to give an incentive to Teva to delay
 23 entry into the market, that would plausibly anticompetitive in and of itself; it is not clear why
 24 Gilead would also have to make a profit sacrifice before its conduct could be deemed a violation
 25 of antitrust law.

26 Defendants suggest that a profit sacrifice is required because only “a profit sacrifice will
 27 provide the necessary basis to infer the potential for patent weakness.” Mot. at 9; *see also* *Actavis*,
 28 570 U.S. at 158 (stating that “[a]n unexplained larger reverse payment . . . would normally suggest

1 that the patentee has serious doubts about the patent's survival"; thus, "the size of the unexplained
 2 reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a
 3 court to conduct a detailed exploration of the validity of the patent itself"). But Defendants'
 4 position is problematic because, even though a profit sacrifice might be one way to infer patent
 5 weakness, it is not clear why there could not be other ways for an antitrust plaintiff to show patent
 6 weakness. More fundamentally, regardless of the strength or weakness of a patent, if a patentee
 7 could give a generic manufacturer an incentive to delay entry even by means other than a direct
 8 reverse payment, that could be a plausible basis for anticompetitive conduct.

9 2. Profit Sacrifice

10 In any event, Plaintiffs do, in fact, assert a reverse payment theory, and thus the Court
 11 considers whether there is any evidence of a reverse payment from Gilead to Teva. In this regard,
 12 the Court bears in mind that a reverse payment (or profit sacrifice) can be more complicated than
 13 might appear at first blush.

14 A reverse payment *can* be, but is not *required* to be, an outright payment of cash to the
 15 generic manufacturer. *See King Drug*, 791 F.3d at 403 ("We do not believe *Actavis*'s holding can
 16 be limited to reverse payments of cash."). As the Third Circuit has underscored, "'economic
 17 realities rather than a formalistic approach must govern,'" and thus *Actavis* should be read
 18 "practically . . . to apply to potentially anticompetitive reverse payments regardless of their form."
 19 *FTC v. AbbVie, Inc.*, 976 F.3d 327, 356 (3d Cir. 2020). Accordingly, the Third Circuit (among
 20 other courts) has held that a patentee's agreement not to sell an authorized generic can be a reverse
 21 payment. *See King Drug*, 791 F.3d at 405 (stating that "a brand's commitment not to produce an
 22 authorized generic means that it must give up the valuable right to capture profits").

23 The Third Circuit has even held that there can be a reverse payment even where it is the
 24 *generic manufacturer* who pays cash to the patentee, and not the other way around. For example,
 25 if a patentee would ordinarily require a generic manufacturer to pay millions of dollars to settle a
 26 patent infringement suit (even though the merits of the patents might be debatable), but, through
 27 settlement, the generic manufacturer pays the patentee only a paltry sum, then it could be inferred
 28 that, effectively, there was a reverse payment because the patentee undercharged the generic

1 manufacturer. *See AbbVie*, 976 F.3d at 355 (noting that, “[i]f parties could shield their settlements
 2 from antitrust review by simply including a token payment by the purportedly infringing generic
 3 manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to
 4 eliminate the risk of competition would escape review”); *see also id.* (noting that, “in the Effexor
 5 XR litigation, we reinstated a complaint alleging a generic applicant delayed entry into the Effexor
 6 market in exchange for the brand-name producer’s agreement not to market an authorized generic
 7 – *even though the generic agreed to pay some royalties to the brand*”) (emphasis added); *In re
 8 Lipitor Antitrust Litig.*, 868 F.3d 231, 255 (3d Cir. 2017) (noting that, in spite of the brand’s
 9 claimed losses of hundreds of millions of dollars and “some likelihood of success given the entry
 10 of [a preliminary] injunction [in favor of the brand], which was affirmed on appeal” (and for
 11 which the brand paid a \$200 million bond), the brand and generic entered a settlement in which
 12 *the generic the brand only \$1 million*; this adequately stated a reverse payment claim for relief).
 13 *But see Mayor of Baltimore v. AbbVie, Inc.*, 42 F.4th 709, 715 (7th Cir. 2022) (suggesting that,
 14 under *Actavis*, a patent holder’s settlement with an alleged infringer for less than its full demand –
 15 but the alleged infringer still pays something to the patent holder – cannot be an antitrust violation
 16 because that is a traditional kind of settlement).

17 Taking into account that a reverse payment can take various forms, Plaintiffs have argued
 18 that there is evidence of a reverse payment in the instant case for two reasons:

- 19 (1) “Gilead recreated Teva’s forfeited regulatory exclusivity through private contract. Had
 20 Gilead created such exclusivity *unconnected* to a negotiation over Teva’s entry date,
 21 the going royalty rate was 90%. The cost to Gilead of foregoing those royalties was
 22 \$264.9 million.” Opp’n at 7 (emphasis added).
- 23 (2) Gilead incurred a risk (even if not great) that the MFE/MFEP would be triggered. If
 24 Teva’s entry date were “accelerated by the MFE+ clause, the date of initial entry
 25 occurs earlier and the period of Gilead’s brand sales without generic competition is
 26 shortened.” McGuire Rpt. ¶ 171.

27 Both reasons are plausible, and Defendants’ arguments to the contrary are not persuasive.
 28 For example, for the theory in (1), Defendants argue that it improperly “treats the creation of more

1 competition as a reverse payment, and the only ‘sacrifice’ at issue is merely a noncognizable
 2 ‘opportunity cost.’” Mot. at 20. But Defendants’ suggestion that an opportunity cost is not
 3 cognizable is not well supported. Although one could characterize a patentee’s giving up the right
 4 to sell an authorized generic a mere opportunity cost, that has been recognized by courts as a
 5 reverse payment. *See, e.g., King Drug*, 791 F.3d at 405. That result is perfectly logical;
 6 opportunities can have value.

7 Defendants’ reliance on, *e.g., Rebel Oil Co. v. Atlantic Richfield Co.*, 146 F.3d 1088, 1095
 8 (9th Cir. 1998), is not persuasive. *Rebel Oil* was a predatory pricing case. In general, predatory
 9 pricing means pricing below cost – with the goal of eliminating competitors. *See, e.g., Cargill,
 10 Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 117 n.12 (1986) (noting that “[m]ost commentators
 11 reserve the term predatory pricing for pricing below some measure of cost, although they differ on
 12 the appropriate measure”); *Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209,
 13 222 (1993) (noting that, when “the claim alleges predatory pricing . . . , a plaintiff seeking to
 14 establish competitive injury resulting from a rival’s low prices must prove that the prices
 15 complained of are below an appropriate measure of its rival’s costs”); *see also Rebel Oil*, 146 F.3d
 16 at 1090 (taking note of plaintiff’s allegation that defendant “charged predatory prices in an attempt
 17 to take away market shares from its competitors” and that, after defendant acquired 54% of the
 18 market, it “then engaged in price gouging, charging [higher] prices . . . to recoup its losses
 19 resulting from the previous low predatory prices”). In *Rebel Oil*, the Ninth Circuit simply
 20 rejected the plaintiff’s argument that below-cost pricing could be shown through the use of
 21 opportunity costs. The court stated that “[o]pportunity costs are vastly different from . . . marginal
 22 or variable costs, and we agree that ‘the use of the concept of opportunity costs [*to show predatory
 23 pricing*] must be held improper as a matter of law.’” *Id.* at 1095 (bracketed information in
 24 original; emphasis added). Even if opportunity costs cannot be used to show predatory pricing,
 25 the instant case is not a predatory pricing case. *See also* Opp’n at 9 (arguing that *Rebel Oil* simply
 26 holds that “‘opportunity cost’ is not the right metric for measuring below-cost pricing in a
 27 unilateral predatory-pricing case, an entirely unrelated legal and economic issue”). Furthermore,
 28 as Plaintiffs point out, their theory here is not that Gilead “pass[ed] up an existing opportunity;

1 [rather], it *created* the exclusivity and gave it to Teva for free” even though it had value. Opp’n at
2 8 (emphasis in original).

3 Defendants further argue that the theory in (1) sets up “an unworkable standard that would
4 require courts to determine the best *business* outcome a company could theoretically obtain, and
5 impose antitrust liability if the company chose a different course” (which is “why courts refuse to
6 treat opportunity cost as a profit sacrifice”). Mot. at 20 (emphasis in original). But the theory of
7 Plaintiffs’ claim is not complicated and does not require extensive second guessing of normal
8 business judgment. Plaintiffs’ point is that Gilead would have charged *some* kind of royalty for
9 the contractual exclusivity but did not charge *anything*. Furthermore, Defendants’ argument that
10 their decisions should somehow be immune from judicial scrutiny would in some ways be an
11 indictment of the rule of reason itself. The Court rejects Defendants’ argument.

12 Finally, Defendants assert that Plaintiffs have created an “impossible Catch-22”:

13 Plaintiffs suggest that charging a first-filing generic manufacturer
14 any royalty *lower* than 90% is a reverse payment. Yet in other
15 cases, the same plaintiffs’ counsel, supported by Dr. McGuire, have
16 asserted that a patent settlement requiring royalties of 25% or *higher*
17 was a reverse payment; there, they reasoned that the 25% royalty
18 rate was improperly “high” because it discouraged the patentee from
19 launching an authorized generic. Had Gilead charged the 90%
20 royalty Plaintiffs suggest it was required to charge, there can be no
21 doubt Plaintiffs and Dr. McGuire would argue that *that* was a
22 reverse payment.

23 Mot. at 21 (emphasis in original). But whether a royalty payment would be anticompetitive would
24 depend on the totality of the facts; Plaintiffs’ point here is simply that in negotiations *unrelated to*
25 a patent settlement Gilead would have charged a 90% royalty (or something at least) for
26 contractual exclusivity, and that, by charging nothing, Gilead effectively compensated Teva for its
27 delayed entry.

28 As for the theory in (2), Defendants make a similar argument – *i.e.*, contending that a
MFE/MFEP that accelerates a generic entry date is pro-competitive and that the sacrifice of an
opportunity cost is not the kind of profit sacrifice required by *Actavis*. But even if there may be a
pro-competitive aspect where there is acceleration, that can arguably be counterbalanced by
anticompetitive aspect: that is, even though acceleration means generic competition comes earlier,

1 it also means delayed competition from other generics (and typically, the more generics there are,
2 the cheaper the generic drugs are). In any event, to the extent there are pro-competitive benefits
3 from the agreement, that factors into the rule-of-reason calculus, one which should be left for the
4 jury.

5 D. Defendants' Daubert Motions

6 Defendants have argued that, if the Court is to deny its motion for summary judgment on
7 the MFE/MFEP claims, it must address their *Daubert* motions to exclude two of Plaintiffs'
8 experts, Mr. Lentz and Dr. McGuire. It does not appear that the *entirety* of the motions related to
9 Mr. Lentz and Dr. McGuire needs to be decided.

10 For Mr. Lentz, Defendants make two arguments: (1) Mr. Lentz is not qualified to opine
11 that the new formulation patents would have been found invalid or not infringed, and (2) his
12 conclusions about both the FTC patent litigation and the new formulation patents conflict with
13 Teva's internal assessment that it was not likely to prevail on either. For purposes of summary
14 judgment, the Court need only address the second argument. As discussed above, Teva's
15 subjective views are not dispositive, and therefore the *Daubert* motion on (2) is denied. The Court
16 need not address (1) because Plaintiffs need not rely on Mr. Lentz's views regarding the
17 formulation patents. They can rely instead on evidence that Teva itself looked favorably on its
18 ability to launch a product in spite of the formulation patents and only belatedly (in February
19 2014) changed its tune, and without explanation.

20 For Dr. McGuire, Defendants contend that he (1) improperly provides legal opinions, (2)
21 incorrectly interprets the Supreme Court's *Actavis* decision, (3) fails to consider Teva's actual
22 views when modeling the parties' negotiations, (4) improperly challenges the credibility of Teva's
23 witnesses, and (5) speculates what Teva and Gilead would have done in the but-for world. At
24 most, the third and fifth arguments are relevant to the motion for summary judgment. Neither of
25 the arguments is persuasive. As discussed above, Teva's subjective views on its likelihood of
26 success are not dispositive. Also, it is not improper for Dr. McGuire to opine as to what a rational
27 company in Teva or Gilead's position would have done.

28 Accordingly, for the limited issues relevant to the motions for summary judgment, the

1 Court denies the *Daubert* motions related to Mr. Lentz and Dr. McGuire.

2 **VII. CONCLUSION**

3 For the foregoing reasons, the Court rules as follows:

- 4 • Defendants' motion for summary judgment on the TAF claims is granted. *See*
5 1378, 1493.
- 6 • Plaintiffs' motion for summary judgment on market power is denied. *See* Docket
7 Nos. 1407, 1501.
- 8 • Plaintiffs' motion for summary judgment on the NGR claims is denied. *See* Docket
9 Nos. 1407, 1501.
- 10 • Defendants' motion for summary judgment on the NGR claims is granted in part
11 and denied in part. The motion is denied, except as to the Prezcobix, Odefsey, and
12 Symtuza Agreements, thus leaving only the Complera and Evotaz Agreements at
13 issue for the NGR claims. *See* Docket Nos. 1377, 1492.
- 14 • Defendants' motion for summary judgment on the MFE/MFEP claims is denied.
15 *See* Docket Nos. 1376, 1491.
- 16 • Defendants' *Daubert* motions as to Mr. Lentz and Dr. McGuire are denied (but
17 only with respect to the specific issues discussed above). *See* Docket Nos. 1406,

18 The Court instructs the Clerk of the Court to file this order under seal. The Court orders
19 the parties to meet and confer to determine which portions of this order may be publicly filed. The
20 parties shall jointly file their request to file under seal within a week of the date of this order.

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1 The status conference set for January 9, 2023, at 3:00 p.m. remains on calendar. The
2 parties shall be prepared to address which of the previously-filed *Daubert* motions still need
3 resolution in light of the Court's summary judgment rulings, as well as next steps.

4 This order disposes of Docket Nos. 1491, 1492, 1493, and 1501, as well as portions of
5 Docket No. 1494.

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7 **IT IS SO ORDERED.**

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9 Dated: January 5, 2023

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EDWARD M. CHEN
United States District Judge

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